UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	MD 15-02641-PHX-DGC
Lisa Hyde and Mark Hyde, a married couple, Plaintiffs,	Phoenix, Arizona **September 28, 2018**
v.	CV 16-00893-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation, and Bard Peripheral Vascular, an Arizona corporation, Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 9 - A.M. SESSION

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Proceedings Reported by Stenographic Court Reporter
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I N D E X

EXAMINATION

EXHIBITS

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

08:31:07 THE COURT: Thank you. Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: Defense counsel, let's start with your Rule 50 motion.

08:31:29 MR. ROGERS: Thank you, Your Honor. Your Honor, Ms. Helm is going to begin and then we're going to switch off a little bit.

THE COURT: Okay, but we've only got a few minutes to do this.

08:31:39 MR. ROGERS: Understand.

THE COURT: We can't go for 15 minutes in argument.

MS. HELM: Thank you, Your Honor.

Your Honor, the first claim on which we move for judgment as a matter of law is the loss of consortium claim. 08:31:57 Under Wisconsin law, the derivative claim for loss of consortium is a claim to recover for the loss of love and affection, companionship, society, the privileges of sexual relations, the comfort, aid, advice and solace, the rendering of marital services, the right of support, and any other 08:32:17 elements that normally arise in a close, intimate, and

harmonious marriage relationship.

To recover, there must be evidence of an impairment or deprivation of those rights resulting from a disabling injury to a spouse. That's *Ballard versus Lumbermens Mutual Casualty Company,* 148 Northwest 2d 65.

Mr. Hyde testified about his worry for Ms. Hyde and his concern for her. He testified -- he -- neither he nor Ms. Hyde testified about any impact that her alleged injuries had on their relationship, their marital relations, or her ability to do the things that she normally did for the family.

There's no evidence from either Mr. Hyde nor Mrs. Hyde that he, for example, had to assume household chores that she normally did, that he had to take over care of their daughter. There's no evidence of any change in their marital or intimate relationship. There was also no evidence that she was not able to share with him her love and affection.

While I respect his worry and concern, that is not an element of the claim for loss of consortium. He does not have an independent claim.

And I reviewed Mr. Hyde's testimony very carefully this morning and he expressed his worry and his concern for his wife. He talked about having to take off work. But nowhere in his testimony or in Mrs. Hyde's testimony is there any description or any evidence of any impact that her alleged injuries had on their marital relationship or the elements of

the claim for loss of consortium.

So for those reasons, plaintiffs have failed to prove the essential elements of a claim of loss of consortium and judgment as a matter of law should be entered on that claim.

THE COURT: All right. Thank you.

Mr. Rogers.

MR. ROGERS: Your Honor, I'm going to talk about the claim for future injuries.

As the Court knows, there's evidence that came in through primarily Dr. Muehrcke that Mrs. Hyde has a possibility of experiencing arrhythmias in the future, and if she does she may need a pacemaker. Your Honor, under Wisconsin law, that is not sufficient for a jury to find future injuries.

Wisconsin law requires that future injuries be established to a probability not a mere possibility. You may recall that Dr. Muehrcke said that there was a possibility, and when asked if he could quantify that in any way, he could not.

Your Honor, there are several cases I'd like to hand up to the court that have discussed this issue and also have a copy of Dr. Muehrcke's testimony on the subject. For that reason, we move under Rule 50 to dismiss the claim for future damages.

THE COURT: Do you have copies for counsel?

08:35:25 MR. ROGERS: I do.

THE COURT: Let me be clear. I think, if I understand you correctly, what you're moving for, Mr. Rogers, is a judgments on the aspect of future damages that would 08:35:59 include implant of a defibrillator; is that right?

MR. ROGERS: That is correct. And any claim for future arrhythmias developing in the future.

THE COURT: All right.

Ms. Helm.

08:36:13 MS. HELM: At this time we move for judgment as a matter of law on plaintiffs' strict liability claim.

Under Wisconsin statute --

MR. MANKOFF: Sorry to interrupt you. I'm having a little trouble hearing. Can you move the microphone.

08:36:27 MS. HELM: Under Wisconsin statute 895.0471(a), in order for a manufacturer to be held strictly liable for defective design, the plaintiff bears the proving -- burden of proving with reasonable certainty that the foreseeable risk of harm posed by the product could have been reduced or avoided 08:36:47 by the adoption of a reasonable alternative design.

The first aspect, first element, of the statute in strict liability is reasonable alternative design.

Plaintiffs have failed -- we submit plaintiffs have failed as a matter of law to prove a reasonable alternative 08:37:05 design as defined by the statute.

08:37:08 The first alternative design that plaintiffs have offered is the Simon Nitinol. And it is important to remember that Dr. McMeeking testified that he was not offering an opinion that the Simon Nitinol was a reasonable alternative 08:37:27 design for Ms. Hyde.

The second important thing in the testimony is that Dr. Henry testified that when he chose the G2X filter, one of the benefits he considered in placing the G2X filter was the fact that it did have the option to be retrieved. And that 08:37:48 was a question. His answer: Yes, yes, definitely.

Dr. McMeeking testified at page 63 of the transcript, lines 3 to 8, that a Simon Nitinol filter is not designed to be retrieved.

He also testified that a Simon Nitinol filter is a 08:38:07 permanent filter and that would indicate it shouldn't be used as a retrievable filter.

Your Honor, quite recently a New York federal court addressed the issue of alternative design in a comparison of a permanent IVC filter to a temporary or retrievable IVC filter. 08:38:28 The case is *Oden*, O-D-E-N, *versus Boston Scientific.* Civil action file number 18-0334. And I have a copy of the case and -- I have copy for the Court. My copy's highlighted, but I'll be happy to give it to plaintiffs' counsel. And we found it on Lexis and not on Westlaw, so I did bring copies.

08:38:54 And what's interesting in that case is the Court said

that a permanent filter is permanent. A retrievable has a different option, it has the option to retrieve. So they're not the same product. An alternative design cannot be a different product.

Your Honor, the analogy is a hard-top car is a car. It's designed to get you -- drive you from one place to another. A convertible car is a car. It has the same intended use, but it has an option. It has -- that is different than the permanent car. Just like the Simon Nitinol is a permanent filter. The G2X or the Eclipse is a permanent filter with the option to retrieve.

So under a number of cases -- and there are no Wisconsin cases interpreting this statute that we've been able to find. But under a number of cases addressing Restatement, Third, cases, the courts have held that even if a product has the same intended use, if it's not the same product, it cannot be a reasonable alternative design.

And specifically in *Brockert*, B-R-O-C-K-E-R-T, versus *Wyeth Pharmaceuticals*, Texas case at 287 Southwest 3d 760, the court held that a plaintiff cannot prove that a safer alternative design exists by pointing to a substantially different product even when the other product has the same general purpose as the allegedly defective product.

That's also consistent with New York who's addressed the Third Circuit -- I mean the Restatement, Third, cases in

08:40:40 *Pinello*, P-I-N-E-L-L-O versus Andreas S-T-I-H-L AG and Company, 211 Westlaw, 1302223.

Your Honor, as a matter of law the Simon Nitinol -- we submit that the Simon Nitinol cannot be considered as a 08:41:05 reasonable alternative design under the strict liability statute.

Likewise, Your Honor, Dr. McMeeking testified about the possibility of an alternative design to the G2X and the Eclipse. His testimony was a filter that had a different 08:41:25 angle coming out at the cap, caudal anchors, and penetration limiters, it had all three design elements, he admitted that he was not aware of any such filter that existed at the time Ms. Hyde's filter was implanted.

Importantly, he admitted that he has done no 08:41:48 calculations, no design, no finite element analysis, no drawings, and no testing of this proposed filter with these proposed alternative designs. And his testimony at -- in the transcript at page 632, line 20, to 633 through the whole page and into 634, I went through every single one of those alleged 08:42:20 design -- alternative designs, and he admitted every single time that he had done nothing other than have the idea.

Your Honor, under Wisconsin law, proposed designs are theoretical only and if not supported with any data, testing, or analysis, may not serve as a reasonable alternative design.

08:42:45 *American Family Mutual Insurance Company versus*

08:42:48 *Electrolux Home Products*, 2014 Westlaw, 2893179.

Your Honor, he admitted -- Dr. McMeeking admitted he came in with an idea, a concept. He admitted that prudent engineering practices required design, analysis, testing, 08:43:12 analysis of the testing, and a whole list of things that engineers must do. He also admitted that he came in here with three ideas: Changing the angle of the cap --

THE COURT: You've covered that ground.

MS. HELM: Okay.

08:43:27 So, Your Honor, as a matter of law we believe plaintiffs have failed to establish a reasonable alternative design and we're entitled to judgment on their strict liability claim.

THE COURT: All right.

08:43:39 MS. HELM: One more.

THE COURT: Okay. You're at 13 minutes.

MS. HELM: Your Honor, we also move for judgment as a matter of law on the punitive damages claim. Under Wisconsin law, punitive damages may only be awarded when a plaintiff 08:43:53 proves by clear and convincing evidence that the defendant acted maliciously towards the plaintiff or in intentional disregard of the plaintiff's rights.

That's Wisconsin statute 8895.043(3).

The standard in Wisconsin is heightened. It is not 08:44:14 willful, wanton, or reckless. It's a higher standard. The

08:44:19 seminal case is *Strenke*, S-T-R-E-N-K-E, *versus Hogner*, H-O-G-N-E-R, 694 Northwest 2d 296.

And under this heightened standard and the law -- actually, in that case they talk about this is a heightened 08:44:37 standard. Under that heightened standard, the frame of mind of the alleged wrongdoer is a necessary consideration in determining whether punitive damages may be imposed.

First, the first part of the statute requires is whether the defendant acted maliciously. To establish that a 08:44:56 defendant acted maliciously, the plaintiff must show by clear and convincing evidence hatred, ill will, desire for revenge, or actions inflicted under circumstances that were -- where insult or injury is intended. Intent is a clear element of the acting maliciously. Again, that's the *Strenke* case.

08:45:21 Your Honor, there is simply no evidence. There's no evidence at all of any intent to harm -- by Bard to harm Ms. Hyde. There's no evidence at all of any hatred, ill will, desire for revenge, or actions to insult or injure her.

The second half of the statute is intentional 08:45:44 disregard. And under the *Strenke* case again, that means that a -- that the wrongdoer acts with the purpose to disregard the plaintiffs' rights or is aware that his or her acts are substantially certain to result in the plaintiffs' rights being disregarded.

08:46:04 Supreme Court of Wisconsin has set forth three

elements that you must show by clear and convincing evidence in order to show intentional disregard.

The first one is that the actions by the defendant were deliberate. The second is there was an actual disregard for the plaintiff's right to safety or health, and third was the conduct -- it's an "and" standard. Third was the conduct was sufficiently aggravated to warrant punishment by punitive damages.

Again, Your Honor, there's no evidence that Bard acted deliberately or with an actual disregard for Ms. Hyde's health or well-being and we would move for judgment as a matter of law on the punitive damages claim.

THE COURT: Okay.

MS. HELM: And I have copies of the cases that I'll bring up as soon as I get them to the plaintiff.

THE COURT: That's fine.

Plaintiffs' counsel.

MR. MANKOFF: Thank you, Your Honor.

Regarding the first claim for loss of consortium, the standard quoted by defense counsel included the impairment of a harmonious marriage. And we did hear testimony yesterday that Mrs. Hyde was waking up at night, that she was suffering from anxiety. And the jury could reasonably infer from that that the injury has impaired their relationship, has caused harm to Mr. Hyde.

08:47:49 Regarding the future risk of harm, as an initial matter, there's no specific claim for future risk of harm. It's subsumed in the category of injury. So I don't believe it's even proper for a Rule 50 motion. But that said, there
08:48:08 is sufficient evidence for the jury to find that there is a future risk of harm.

Dr. Muehrcke testified she's at some risk for arrhythmia at 884. And there are Wisconsin cases that support the idea that when there's testimony that there's some future
08:48:30 risk, that is sufficient to get to the jury. I would direct your attention to *Ehlinger v Sipes*, 454 Northwest 2d 754.

This was actually a case involving failure to diagnose. It was a couple of twins and the doctor -- the doctor failed to determine that there were twins and failed to
08:48:54 take any steps to try to lengthen the pregnancy, so the twins were born prematurely and injured. And there's no testimony about any amount of how much the increase in -- any increase in pregnancy, whether that would have been successful. There was no quantification of the risk of harm that could have been
08:49:19 avoided, and the court ruled that was sufficient.

The court cited approvingly of the Restatement, Second, of torts Section 323 which says that someone can be liable for failing to reduce a risk of harm if the failure to exercise such care increases risk of such harm. Again, no
08:49:39 quantification required there.

08:49:41 The *Bleyer* case that defendants cited today also talks about future harm, I believe without any quantification, and the jury verdict in that case was affirmed.

And finally *Brantner v Jenson* at 360 Northwest 2d 08:50:00 529.

The *Ehlinger* case and this case are Wisconsin Supreme Court cases.

There was testimony in that case that a future surgery might be necessary but there was no indication about 08:50:13 how probable. Similar to this case. And the court held that just the fear of surgery may be reasonably certain even if there is no certainty that the surgery will occur and even though the physician cannot testify to a reasonable degree of medical probability that the consequences feared will occur. 08:50:30 And in that case the court upheld an award -- I'm sorry, denied -- I believe it denied a directed verdict motion for mental distress for that fear of future risk.

Turning to alternative design, we would submit there are at least eight alternative designs that the jury heard 08:51:05 evidence of and could reasonably conclude were reasonable alternative designs in this case.

First, the jury could conclude from the evidence that Ms. Hyde received a G2X filter. The defendants admitted there was, at best, circumstantial evidence and that it was a jury 08:51:31 decision which filter she received.

08:51:33 If they conclude that she received the G2X filter, then the Eclipse was a reasonable alternative design and defendants have claimed that that design with the electropolish reduced the risk of fracture.

08:51:44 Second, Dr. McMeeking testified that caudal anchors were a reasonable alternative design, and Exhibit 2249 indicates that the Greenfield filter had caudal anchors, at least as of 2006. So that was a design commercially available.

08:52:02 Dr. McMeeking also testified about penetration limiters and Bard did, in fact, design a filter with penetration limiters.

So his not having prototyped or designed or tested such a filter does not prevent the jury from reasonably

08:52:23 concluding that that was an alternative design.

Dr. McMeeking also testified that the chamfer of the cap of the G2X and Eclipse filter were defectively designed and that rounder chamfer would have been a reasonable alternative design, and he testified at 621 that the SNF had a

08:52:48 better cap. And that is also commercially available. Even if you don't find that the SNF filter itself is an available reasonable alternative design.

That said, we believe the SNF is -- does qualify as a reasonable alternative design because the G2X and Eclipse

08:53:07 filters convert into permanent filters at six months. And

08:53:11 Mrs. Hyde testified she believed the filter would remain in place for the rest of her life.

Other alternative reasonable designs include the ALN and OptEase filters which there's evidence to show that they 08:53:27 had fewer fractures. Most notably Exhibit 1940. I believe Dr. Streiff testified to that as well.

Finally -- I've lost count how many I mentioned, but the two-tiered -- Dr. McMeeking testified the two tiered design from the SNF was a safer design, and so that also could 08:54:05 have been a design component that was commercially available that could have been incorporated.

And I believe that's seven.

An eighth alternative design would be a G2 or G2X, Eclipse, that was indicated for that six-month time period.

08:54:27 And there are cases -- I did not find a Wisconsin case but there is a case from the Western District of Pennsylvania which cites Restatement, Third, which I believe applies in this case stating a jury could reasonably conclude that a feature could have been designed -- sorry. That a 08:54:42 prototype is not necessary. So some of these features, the jury could conclude, could be designed into the G2. That is *Lynn versus Yamaha Golf-Car Company*, 894 F.Supplemental 2d 606. That's Western District of Pennsylvania 2012.

Regarding punitive damages, the evidence in this case 08:55:10 is very similar if not stronger than the evidence in the Jones

and Booker trials.

Again, we saw that Bard started with the Recovery filter and in a short-term pilot study the only time it was challenged with a clot it failed and they put it on the market anyway and they never determined the root cause of the failures. They saw fractures and migrations and they kept it on the market while they quickly tried to design a fix that they didn't sufficiently test, namely the G2 filter. They launched it without even a pilot study. And they created this unique problem of caudal migration.

There's evidence in this case that Mrs. Hyde's filter did migrate caudally, even if minimally, and there was testimony that penetration is a form of caudal migration. Which clearly occurred in this case.

The EVEREST study was not a safety study, it was really to increase and maintain market share by gaining retrievability indication. And the medical monitor had serious concerns about the safety and stability and that more than half of the filters moved and tilted and he discussed stopping the study or redesigning the filter, but he didn't have authority to do that. Of course Bard went ahead any way. And probably the only doctor involved in the submission to the FDA regarding the EVEREST study said that the filter did not demonstrate substantial equivalence and that claim should not be made. But that claim was made anyway. Then Bard turned

around and --

THE COURT: Who is that you're referring to?

MR. MANKOFF: That was Dr. Lehmann.

THE COURT: All right.

We've got just a couple minutes before we bring in the jury.

MR. MANKOFF: Okay. Bard turned around and marketed the filter for lifetime implantation, which meant even though they tested it for ten years for fatigue resistance, they were marketing it for 60 or more years of implantation.

And Bard -- we heard that Bard manipulated tests, and this is evidence of a conscious disregard for the rights to Mrs. Hyde. They increased the testing temperature so it didn't reasonably mimic the environment of use. They only -- with the Recovery they only passed the migration tests when the temperature was 104 degrees. And they maintained this temperature through the G2 testing.

When the G2 was on the market, they found an unacceptable risk. And they found statistically significant differences in the performance of their product relative to the predicate devices and relative to competitor devices.

I'm cognizant we don't want to keep the jury waiting, so unless the Court has questions, that concludes my argument.

THE COURT: Okay. Thank you.

I'm going to take this under advisement. If I think

09:01:04 testimony of Dr. Grassi.

You may continue, Mr. Condo.

MR. CONDO: Thank you, Your Honor.

Good morning, ladies and gentlemen.

CLEMENT GRASSI, MD,

recalled as a witness herein, after having been previously sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N (CONTINUED)

BY MR. CONDO:

09:01:09 Q Good morning, Dr. Grassi.

A Good morning.

Q Yesterday when we broke I think we had spent a little bit of time not only talking about your qualifications but talking about the purpose for the SIR guidelines that were developed

09:01:22 for inferior vena cava filters.

To help us all return to that point, would you tell us again what the purpose was for the development of those guidelines.

A The purpose of the guidelines was to fill a need for those

09:01:41 working with inferior vena cava filters, and especially practitioners, so they could have a document that they could reference. And its goals were to educate and inform and summarize for them essential data for those using IVC filters.

Q And what was the data that was summarized, sir?

09:02:10 A Well, it started with a review of the literature, that is

09:02:15 the world literature, on the subject. And through a process of committee meetings and the formation of the document that led to the publication.

Q Were you involved in that process?

09:02:30 A Yes, I was.

Q What was your role in the process?

A Well, I was pleased to have been identified as a person to lead the processes as the first author of the document because my colleagues knew of my interest in inferior vena cava

09:02:48 filters. And so I was the first author and lead author in that project.

Q What does it mean to be the first author or lead author in a peer-reviewed article?

A What it means is that that person is the leadership

09:03:03 individual. He or she would speak with the other members on the committee, would work with the SIR support staff, and would really spearhead the whole process, which took just about two years.

Q Now, can you summarize the full process that took two

09:03:24 years to develop the guidelines.

A Well, it was multi part. It started with our identifying, with the SIR support staff at their office, that we needed to do a literature search. And the world literature was collected using Google Scholar, Medline, PubMed, and other

09:03:48 search engines.

09:03:50 From those articles, which were literally thousands, we began by reviewing what we thought were the most pertinent references. Those references went to the working committee.

I would speak to committee members, identify people 09:04:08 who I thought would be suitable and talented in terms of writing or assisting with certain parts of the document. And, as a second step, individuals would contribute and we would have conference calls, usually a weekday evening at 8:00 p.m. to 10:00 p.m. And there were also at least four meetings in 09:04:36 person, and those occurred at the annual society meeting of the Society of Interventional Radiology and also at the Radiological Society of North America meeting, which is held in Chicago each year.

Q And were drafts developed of the guidelines?

09:04:55 A They were.

Q And were those circulated and to whom?

A Yes. And so the drafts went to all committee members and a preliminary document was produced with my leading that. At that point the document was then again reviewed, this time by 09:05:16 the executive committee of the Society of Interventional Radiology, or I'll refer to it as the SIR. And at that point after their input, we also called for -- invited commentary with public -- prepublication, really, of the document in electronic form so that other interventionalists could weigh 09:05:44 in on the document, on the text.

09:05:48 At the conclusion of that process and that approval, which, again, as you can imagine, took some time, the entire document was then submitted in a prepublication state to the official journal of the SIR called the JVIR, Journal of
09:06:07 Vascular Interventional Radiology, and that went through its own peer-review process by the editor.

Q Thank you.

MR. CONDO: If we could, Scott, call up Exhibit 7312.

BY MR. CONDO:

09:06:30 Q Doctor, is Exhibit 7312 the SIR guidelines that emerged as a result of that two-year process you've just described for the jury?

A Yes, it is.

Q Can you please read the title.

09:06:44 A Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism.

Q And you said this was a peer-reviewed article?

A That's correct.

09:06:59 Q And in what journal did it appear?

A In the official journal of the SIR, which is called the JVIR or Journal of Vascular and Interventional Radiology.

Q And how many members are there or were there in 2001 of the SIR?

09:07:17 A At that time I would estimate approximately 5,500 members.

09:07:25 Q And were these guidelines, when published, also made available to others who might have an interest in IVC filters?
A Yes, they were, because, as I mentioned, in addition to our print prepublication versions, this was placed on the SIR
09:07:41 website electronically so that others had access and could read it.
Q I may have asked you this yesterday, and if I did, I apologize, but are these guidelines used in teaching hospitals?
09:07:55 A Yes, they are.
Q And what is your understanding as to how members of the medical community make use of these guidelines, sir?
A My understanding is they refer to them, read them, and consult them when dealing with inferior vena cava filters and
09:08:16 looking for information in summary fashion.
MR. CONDO: Your Honor, we offered Exhibit 7312.
MR. LOPEZ: 802(12), Your Honor. Objection. 802(18), I'm sorry.
THE COURT: Well, let's talk about this for just a
09:08:36 minute at sidebar, Counsel.
MR. LOPEZ: Did you say sidebar, Your Honor?
THE COURT: Yes, please.
(Bench conference as follows:)
THE COURT: Mr. Lopez, I assume you mean 803(18)?
09:09:00 MR. LOPEZ: I do. I'm sorry. Did I say 802?

09:09:01 THE COURT: I assume your objection is it's a learned treatise and therefore can only be read and not admitted?

MR. LOPEZ: Right.

THE COURT: What's your response, Mr. Condo.

09:09:10 MR. CONDO: Same response as last time. It's offered for notice and we propose it be admitted with the limiting instruction Your Honor has given previously.

THE COURT: So in the previous trials, at least I know in the Jones trial because I checked my notes this

09:09:22 morning, I admitted it with the instruction the jury was not to consider the article for the truth of what's asserted in the article, namely these are truthful findings, but, rather, for notice of what the medical community was told by the SIR guidelines. What's your response on that?

09:09:42 MR. LOPEZ: That was a good plan. I probably should have said 401, 402, 403. It's a 2003 article. It's relevant to that time period, maybe, and only relevant on permanent devices. And there's no -- no one testified that they used that 2003 article now to determine whether or not they're

09:10:03 acceptable rates of migration, all these other complications. Especially it has nothing to do with design. Doesn't talk about the design of these devices.

It's just going to mis- -- if there's anything that's going to mislead and confuse this jury and be prejudicial to

09:10:18 our design defect case, it's their representation that this

09:10:22 article somehow is the acceptability of the rates of complications of these devices and therefore how can these devices possibly -- I mean the Bard devices possibly be unreasonably dangerous when they're putting up rates that are
09:10:39 .14, .17, .16 against -- which are reportable rates against rates that are in this from medical articles of devices that are now 30, 40 years old and some not even on the market any more.

I -- we've made this argument before, but I think now
09:11:01 that we're talking about a case where design is an issue, that doesn't discuss the differences in the risks of the design.

THE COURT: Okay.

MR. CONDO: I believe this was all addressed in your minute entry, your motion in limine order on the relevancy and
09:11:18 appropriateness going to design defect.

This goes to the notice of the medical community and manufacturers as to -- and there is -- there's not going to be an argument and we're not going to say these are acceptable rates. In fact, there will be a question in my outline that
09:11:38 says is this an intent to establish acceptable rates and the witness said before of course not.

THE COURT: What is your response to Mr. Lopez's argument that this is a 2003 guideline that -- well, might have been earlier.

09:11:53 MR. CONDO: It's 2001.

09:11:55 Well, their whole case is built on the series of predicate devices. They had put in evidence of the Recovery filter, which is a permanent filter. This was what the state of the art was in terms of the knowledge of the industry at
09:12:07 that time.

They then carried it forward and said G2 is bad, G2X is bad, Eclipse is bad. This goes exactly to the state of the knowledge of the industry in 2001 when these predicate devices, as they have argued it, were being designed and when
09:12:28 others were making decisions.

Now, there is a later. We're going to come into the 2016 SIR guidelines and we'll show those, if permitted, or read those, if permitted, to show those rates. Those include the retrievable filters.

09:12:47 But this is all part of, as Your Honor recognized, I thought, in the motion in limine, this is all part of the design defect that goes to the jury's decision as to whether or not this is a reasonable design.

THE COURT: Are you going to be objecting on the
09:13:03 2016?

MR. LOPEZ: There's one section in it that I think is relevant, and that is the SIR clarifying that their use of thresholds and trackable events is not meant to be the SIR's -- I can't remember the language. But, Your Honor, I'm
09:13:25 going to object to all of the data that's on there. It says

09:13:29 the rate's zero to 100 percent on some of these.

THE COURT: So you are going to object to admission of the 2016 guidelines?

MR. LOPEZ: Yes.

09:13:38 THE COURT: What will the basis be?

MR. LOPEZ: Well, 803(18) again, and plus it deals with articles that show rates between zero and 100 percent. It's going to mislead this jury that -- these things are dangerous. What's -- what's .16, .17, .27. It's just going

09:13:59 to mislead the jury. These are medical -- I can't cross-examine -- I can't -- if you gave me time, I could walk this jury through every single one of those references and show -- excuse me, show them why these are not relevant to this case and show them that some of these additional

09:14:20 percentages that are in the most recent SIR are because of Bard's filters.

THE COURT: Okay. I understand your position.

Give me a minute.

All right, Counsel, this is my conclusion on this

09:15:39 issue:

803(18) becomes relevant only if information is being offered for the truth of the matter asserted. Information that is not being offered for the truth of the matter asserted is not within the hearsay rules and therefore not within

09:16:08 803(18).

09:16:12 Defendants are proposing that they offer these SIR guidelines not for the truth of the matter asserted within them, namely that these are the rates reflected in the literature through this literature search but, rather, to
09:16:31 establish the knowledge of the medical community concerning what were rates.

In other words, what did the medical community understand from the SIR, particularly the interventional radiology community, understand from the guidelines about
09:16:54 rates that had been reflected in medical literature.

The question in my mind that I've been pondering is whether in this case under Wisconsin law that knowledge within the community is relevant. Is that a fact that these ought to be admitted to address?

09:17:15 Under the Wisconsin statute, the jury has to consider not only whether there was a reasonable alternative design but also whether the failure to adopt a reasonable alternative made the product not reasonably safe.

I've already concluded that in addressing the
09:17:35 question of whether the product was not reasonably safe, it's relevant for the jury to understand what doctors knew, both through the IFU, what they didn't know, stuff that plaintiffs have brought out that weren't told to them, so that they could decide whether the Bard filters were reasonably safe in the
09:17:54 hands of doctors given what doctors knew.

09:17:57 I think part of what doctors knew is the SIR guidelines. And the knowledge of the medical community is, therefore, a relevant fact in this case.

I do not believe that it is unfairly prejudicial
09:18:13 under Rule 403 because plaintiffs can bring out the fact that the guidelines are not manufacturing standards, that the SIR said explicitly, I assume the 2016, they're not manufacturing standards and they therefore did not establish sort of safe haven for Bard. I think that can all be brought out.

09:18:37 And the jury can then put into the mix of their assessment as to whether the product was reasonably safe, what the doctors knew about the SIR guidelines.

So I'm going to admit this exhibit and the 2016 with the limiting instruction I gave in the Jones case, that it's
09:18:53 not for the truth of what's in the article but, rather, for the knowledge the medical community had.

MR. MANKOFF: Your Honor, may I make a brief record?

THE COURT: Yes.

MR. MANKOFF: I believe what the rates show are only
09:19:08 relevant to what doctors knew if they're actually true. So then it would be for the truth of the matter. Further, I don't believe there is any evidence Dr. Henry was aware of this article or any of the SIR articles, so that would also make it not relevant.

09:19:24 THE COURT: Okay. I understand that point.

09:19:26 On the second point, I haven't understood the question to be whether this product was not reasonably safe in a specific case. It's whether, when launched, it was not reasonably safe. So I'm not sure Dr. Henry's knowledge 09:19:43 controls the jury's determination of what was or was not reasonably safe. I mean, you can make that argument, but I don't think that's the determinative fact.

Were you going to say something?

MR. LOPEZ: One thing, Your Honor. To be honest, the 09:19:55 article as it's read, as it is, my main concern is the way it's represented by counsel, by witnesses, that this somehow establishes an acceptable rate. In fact, you even said that before trial, I think, when we were talking about those rates.

THE COURT: I said what?

09:20:14 MR. LOPEZ: You said that this was adopted by the SIR as an acceptable -- that these were acceptable rates. And they're not. The article -- I can cross-examine on that, too. But I just -- I don't -- the thing that bothers me most about these two articles is the way it's being represented by 09:20:32 witnesses and counsel about what they really say. I mean, he's testified -- you know what, I'll cross-examine.

THE COURT: I think all of that is fair cross-examination and closing argument.

MR. LOPEZ: Okay.

09:20:44 THE COURT: All right.

09:20:45 (Bench conference concludes.)

THE COURT: Thanks for your patience.

Ladies and gentlemen, I'm going to give you an instruction in connection with the exhibit that is about to

09:21:08 come in to evidence.

You remember at the beginning I indicated that there may be evidence that comes in for a limited purpose and then I give a limiting instruction.

We're talking now about Exhibit 7312. I'm going to

09:21:22 admit it in evidence, but only for a limited purpose.

You are not to consider Exhibit 7312, which are the SIR guidelines, for the truth of what is stated in the guidelines. In other words, you shouldn't read it as proof that what is in the guidelines is a true statement. We're not

09:21:43 admitting it for the truth of the matter asserted. We're admitting it only so that you can consider what the medical community understood from the SIR guidelines. So it goes to what's in the head of doctors and what doctors knew.

The parties disagree on the significance of the

09:22:03 guidelines and you'll hear those arguments. But it's not admitted for the truth of what's in them but rather simply as evidence of what the medical community heard and received from multiple sources about IVC filters and other medical devices.

So with that limiting instruction, Exhibit 7312 will

09:22:24 be admitted.

09:22:25 (Exhibit 7312 admitted.)

MR. CONDO: Thank you, Your Honor. May we publish?

THE COURT: Yes, you may.

09:22:38 MR. CONDO: Could you zero in more closely on the list of authors.

BY MR. CONDO:

Q Dr. Grassi, who were some of the other individuals who served as authors on these guidelines along with you as the lead author?

09:22:56 A The other individuals were also practicing physicians, interventional radiologists, and very active in the SIR and in percutaneous interventions in general, and many were considered to be thought leaders on the subject.

Q Thank you.

09:23:20 MR. CONDO: Scott, if you could pull up first Table 1.

BY MR. CONDO:

Q Can you explain to the jury what complications are as shown in Table 1 of these guidelines.

09:23:38 A Yes.

Q What definitions was used to characterize the event is a better question.

A Yes. Complications are adverse events or occurrences as evidenced in patients. And several of them were listed here

09:23:58 on this Table 1.

09:24:00 Q And death was one of the complications?
A Yes.
Q Based on this extensive medical literature search, was a reported rate established for death from IVC filter
09:24:15 complications by the SIR guidelines?
A Yes.
Q And what is that reported rate?
A That rate is 0.12 percent.
Q And was a threshold established for the reported events of
09:24:32 death, adverse events of death, involving complications from IVC filters?
A Yes.
Q And what was the threshold?
A The threshold reported is less than one percent.
09:24:45 Q And this is in a survey of all medical literature that was done over a two-year period between 1999 and 2001?
A Yes.
Q Now, to be clear, the SIR guidelines, when they establish a threshold number, never intended to establish acceptable
09:25:04 thresholds for these complications, did they?
A Correct.
Q What is the threshold? Explain to the ladies and gentlemen of the jury what the threshold numbers mean.
A The threshold, what that means is a level which would
09:25:23 prompt a quality assurance review. It's important to

09:25:27 understand this a quality assurance document.

So if a doctor, he or she, or group of doctors, observed these threshold numbers in their own practice, the recommendation of the SIR and of the committee is that this 09:25:46 would prompt them to conduct their own quality assurance review. That is, see what they were doing, how their practice looked, and if there were any specifics that contributed to those numbers.

Q And there are numbers in parentheticals after each of the 09:26:06 described complications. What are those numbers in parentheticals?

A Yes.

On the left-hand part of the table, those represent the references or citations which were included in the 09:26:22 particular topic.

For example, recurrent pulmonary embolus.

Q So this was the source of the information that was used to establish the information in the guidelines?

A Yes. This would not have been the only reference or 09:26:39 citation, but these were the references or citations which, in the opinion of the committee, were the most relevant.

MR. CONDO: Can we pull up, Scott, the last page of Exhibit 7312 to show the jury the list of references.

And can you zoom in on, say, the bottom half of this 09:27:05 under Appendix 2, Methodology. Across the page.

09:27:09 BY MR. CONDO:

Q So we see a section there that says References.

A Yes.

Q So when the ladies and gentlemen of the jury look at this, 09:27:21 each complication rate or threshold rate or other reference can be found in this list of references.

A That's correct.

Q Okay.

If you'd take that down. Can we go to table number 09:27:36 2, please.

7312. I'm sorry, Scott.

BY MR. CONDO:

Q Table 2 refers to something identified as trackable events. Can you explain to the ladies and gentlemen of the 09:28:02 jury what the definition of trackable events was as used by the SIR in these guidelines.

A Yes. Trackable events would represent other occurrences, other things which were observed which would not necessarily be adverse events or complications for the particular patient.

09:28:21 So it's important to understand these were things which, in the opinion of the committee and in my opinion, we felt would be pertinent for those working with IVC filters, especially physician interventional radiologists, to look at and review and be aware of in their own practice day to day.

09:28:45 Q And for each of these trackable events, there were

09:28:49 reference sources cited in the SIR guidelines; correct?
A Yes.
Q There is an entry for migration. Do you see that, sir?
A I do.
09:29:07 Q Does that include both caudal and cranial migration?
A Yes, it would.
Q All right. Let's go through each of them.
For penetration --
MR. CONDO: Can you highlight "IVC penetration."
09:29:24 BY MR. CONDO:
Q How many reference sites are cited for the information that was used to establish that rate?
A In this citation, there are seven.
Q And what did the SIR guidelines -- I'm going to have a
09:29:44 hard time saying SIR through this trial. The SIR guidelines establish as the reported rates in the medical literature for IVC penetration?
A Between zero and 41 percent.
Q And are those reported events as experienced by doctors in
09:30:07 their individual offices as reported in the medical literature?
A Yes. They would be events that would be experienced by interventionalists, seen on imaging, and these were numbers which were observed and which were reported in the literature.
09:30:28 Q Now, if we look at migration, can you tell the ladies and

09:30:34 gentlemen of the jury how many reference citations appear for the reported rate for migration.

A There appear to be approximately 10.

Q And what was the reported rate of migration as established

09:30:55 by the SIR guidelines in this study?

A Between zero and 18 percent.

Q And for filter fracture, how many reference citations were provided?

A There were two.

09:31:14 Q And what was the reported rate established by the SIR guidelines from the medical literature for filter fracture?

A Between 2 and 10 percent.

Q These rates involve only permanent filters, correct, sir?

A They do because it's important to understand at the time

09:31:46 of the organization and writing of this document, permanent filters for the IVC were the filter type that was available to doctors.

Q These rates include filter manufacturers other than Bard or NMT; correct, sir?

09:32:06 A Yes.

Q Now, the SIR guidelines were updated again in 2016, weren't they?

A Yes.

MR. CONDO: If we could see Exhibit 6842, please.

09:32:28 BY MR. CONDO:
Q And were the SIR guidelines as updated in 2016, did they go through the same general process as the 2001 original SIR guidelines?
09:32:47 A To the best of my knowledge, they did. And of course since there was the prior document which we just discussed, they would have referenced that and updated and added information to the newer one.
MR. CONDO: Your Honor, we would offer Exhibit 6842.
09:33:11 MR. LOPEZ: Objection as we said at sidebar, Your Honor. 803(18).
THE COURT: All right. Ladies and gentlemen, I'm going to admit Exhibit 6842 with the same instruction. You are not to consider 6842 for the truth of what is contained in
09:33:27 the guidelines, but, instead, simply for knowledge that was had among the medical community at the time.
(Exhibit 6842 admitted.)
MR. CONDO: May we publish, Your Honor?
THE COURT: You may.
09:33:40 MR. CONDO: Scott, could you enlarge the top half through the title, please.
BY MR. CONDO:
Q What is the title of Exhibit 6842, sir?
A ACR-SIR-SPR Practice Parameters for the Performance of
09:33:57 Inferior Vena Cava, in parenthesis IVC, Filter Placement for

09:34:03 the Prevention of Pulmonary Embolism.

Q This Exhibit has a different title than the last Exhibit 7312. Are these the updated SIR guidelines?

A It does have a different title. And by way of

09:34:20 explanation, since this is published by --

Q Let me ask you the next question because we need to go by question and answer. But this is what would be considered the updated SIR guidelines?

A Yes.

09:34:33 Q All right. Now, explain to the ladies and gentlemen of the jury the references to ACR and SPR and how this document came to be.

A Yes. The ACR, or American College of Radiology, SIR, and the SPR, which stands for Society of Pediatric Radiology,

09:34:53 published these practice parameters in their format as a print and electronic publication. So because this overall body was doing the publication, they adopted the format which you see here in terms of the text differences.

Q So ACR is the American College of Radiology?

09:35:19 A Yes.

Q And how many members, to your knowledge, are members of the American College of Radiology?

A To the best of my understanding, more than 30,000 members now.

09:35:30 Q And is SPR a reference to the Society of Pediatric

09:35:35 Radiology?
A Yes.
Q And is that also a large professional organization?
A Fairly large organization as well.
09:35:44 Q Are these -- was this publication peer reviewed?
A Yes.
Q Did it appear in a reliable professional journal?
A Yes. It appeared from, and as I mentioned the publication by the ACR, which is definitely a major and reliable society.
09:36:08 Q And were these guidelines distributed and made available to members of the American College of Radiology, the Society of Interventional Radiologists, and in fact anyone else who had a reason to be interested in IVC filters?
A Yes. They were available to the people that you mentioned.
09:36:27 Q Did these guidelines concern both permanent and retrievable filters?
A These did because these were published chronologically in 2016.
09:36:39 Q And do the guidelines -- these guidelines in Exhibit 6842 have tables 1 and 2 just like the 2001 SIR guidelines?
A Yes.
MR. CONDO: Would you please pull up Table 1.
And would you -- thank you, Scott.

09:37:10 BY MR. CONDO:
Q It appears as if Table 1 adopted the same style as the 2001 SIR guidelines.
A Yes, it did.
09:37:22 Q Now, we have a reported rate for deaths in all of the medical literature through 2016 for deaths in these guidelines. What was established as a reportable rate?
A The reported rate is 0.12.
Q Is that the same rate as was reported in the 2001
09:37:44 guidelines?
A It is.
Q And what threshold was established for death complications by the 2016 guidelines?
A Less than one percent.
09:37:56 Q Is that the same number as the 2001 threshold for death as a complication?
A It is.
MR. CONDO: Can we go to Table 2, please.
BY MR. CONDO:
09:38:16 Q Table 2 appears similar to the format utilized in the 2001 guidelines.
A Yes.
Q What is the reported rate for IVC penetration according to the 2016 guidelines?
09:38:32 A The reported rate is zero to 100 percent.

09:38:37 Q And what is the reported rate for migration of filter and filter components?
A The reported rate is zero to 25 percent.
Q What is the reported rate for filter fracture in 2016 SIR
09:38:53 guidelines?
A Zero to 50 percent.
Q And do these rates all come from the medical literature reviewed by the committee established in the guidelines?
A They would. And the references which you see are cited
09:39:14 here.
Q All right. Let's go back up to filter fracture. There are, by my count, 34 citations or references listed.
A Yes.
Q You don't need to count them, but accept that. If I'm
09:39:33 wrong, someone will correct me.
Are any of the articles cited for filter fracture actual clinical studies of the Eclipse filter?
A No. To the best of my knowledge, the Eclipse filter is not included in these.
09:39:52 Q And you've reviewed these 34 references in preparation for your testimony today; correct, sir?
A I have had a chance to review them either in whole or in part.
Q And do any of the articles cited for filter fracture
09:40:06 involve the G2X filter?

09:40:08 A To the best of my knowledge, no.
Q Now, let's go up to migration of filter and filter components.
Have you reviewed the references cited for the
09:40:23 reported rate established for migration of filter and filter components?
A Yes.
Q Do any of the reported references involve clinical studies of the G2X or the Eclipse filters?
09:40:39 A Again, to the best of my knowledge, no, they do not.
Q And if we go up to penetration.
I would ask you the same question: Do any of the reported references include studies, clinical studies, involving the G2X or the Eclipse filter?
09:41:00 A To the best of my knowledge, these do not.
Q If none of the reference materials, citations, includes specific citations to articles involving clinical studies of the G2X or the Eclipse filters, what conclusion do you draw from that with respect to the influence of fractures,
09:41:29 penetration, or migration of those filters, Bard filters, on the reported rates?
MR. LOPEZ: Objection, Your Honor, this is not in his report.
THE COURT: Is this in the report, Mr. Condo?
09:41:42 MR. CONDO: I believe it was covered in prior

09:41:45 testimony on pages 1539 to 1542.

THE COURT: Is that deposition testimony?

MR. CONDO: It is not, Your Honor.

THE COURT: Is it in deposition testimony or the

09:41:56 report?

MR. CONDO: It is not in either.

THE COURT: Okay. Objection is sustained.

MR. CONDO: Thank you, Your Honor.

BY MR. CONDO:

09:42:08 Q Final question, Dr. Grassi. Series of questions. Do you have an understanding that some witnesses have offered opinion testimony that perforation, tilt, and filter migration are interrelated and contribute to filter fracture?

A Yes. I've heard that opinion expressed by some.

09:42:32 Q To your knowledge, in the medical literature has there been any study proving that tilt, migration, and/or perforation increases the risk of filter fracture?

MR. LOPEZ: Objection, Your Honor. Not in his report.

09:42:46 THE COURT: Is that disclosed, Mr. Condo?

MR. CONDO: I believe. Page 10.

THE COURT: Of the report?

MR. CONDO: Of the report, yes, Your Honor.

THE COURT: Objection is overruled based on the first

09:43:09 full paragraph on page 10.

09:43:12 BY MR. CONDO:

Q The question to you, sir, was, to your knowledge in the medical literature has there been any study proving that tilt, migration, and perforation together increase the risk of

09:43:30 filter fracture?

A To the best of my knowledge there is no study that has shown or proved that relationship.

Q There is no study that establishes the interrelationship or interrelatedness of those three conditions? Is that what

09:43:52 you're saying?

A Yes. What I'm saying is that in my view, there's no study, again, to the best of my knowledge, that proves the interrelated nature or pathogenesis of the factors which you mentioned.

09:44:11 Q Final question, sir. To your knowledge, has the SIR recommended that physicians stop using IVC filters?

A No, it has not.

MR. CONDO: Thank you, Your Honor. I have no further questions.

09:44:24 THE COURT: Cross-examination?

MR. LOPEZ: Yes, Your Honor.

C R O S S - E X A M I N A T I O N

BY MR. LOPEZ:

Q Morning, Dr. Grassi.

09:44:46 A Good morning.

09:44:47 Q I pronounce it Grassi but I think you pronounce is Grassi. Dr. Grassi, is that how you pronounce it?
A That would be fine.
Q No, I want to pronounce it the way you and your family
09:44:56 pronounce it.
A Yes, that's correct.
Q Grassi? Okay.
I'm actually going to start kind of where Mr. Condo left off. He asked you questions about whether or not there
09:45:07 were any clinical studies that were in the SIR with the most recent guidelines about fractures and migrations and other problems with the G2, G2X, or Eclipse. Remember those questions?
A Yes, I do.
09:45:26 Q Well, the fact is that Bard has never sponsored such a study, so no such study would exist; true?
A That's correct. I'm not aware of any Bard-sponsored study on that topic.
Q I mean, as a matter of fact, I think back in 1990 you were
09:45:46 urging the IVC filter manufacturing industry to conduct those kinds of studies, long term safety and effectiveness study. Do you recall that article in 1990?
A Yes, I do. I was certainly interested in there being more information and education on the subject in general.
09:46:15 Q So naturally there would not be any references in any

09:46:21 article written today about any clinical study performed by Bard or on Bard products sponsored by Bard because no such studies exist; true?

A Well, perhaps you could narrow down your question a little 09:46:37 bit for me. In terms of a study of filter fracture, penetration, perforation, is that the subject that you're asking?

Q Doctor, is the bottom line is that Bard has not conducted a study to see how prevalent their G2, their G2X, or their 09:46:58 Eclipse filter is to fracture and to have a fracture embolize to people's hearts and lungs. True?

A In trying to answer that question as accurate as I can, I'm not aware of any study published in the literature, world literature or literature available to me, on that subject. 09:47:20 That's correct.

Q I don't want the jury to be confused. We've heard the phrase "reported rates" every day in this trial from opening statement until this morning.

When the SIR article that we've been talking about 09:47:33 uses the phrase "reported rates," that means that somebody found an article that talked about one filter in some instances, a case report, and there was a fracture in that case report, so naturally that would be 100 percent reported rate captured by that literature review. Is that a fair 09:47:59 statement?

09:48:00 A Well, that's a bit of a hypothetical question but I'll say certainly, if a study were conducted of a small number of patients as you described and there were fracture in those patients, then mathematically that would constitute
09:48:16 100 percent, yes.
Q Right. So -- and the same is true with all of these rates. These are just people that -- doctors that have looked at a patient population, and if they find in looking back at a patient population that they found ten perforations, that
09:48:36 would be reported as a 50 percent perforation rate; correct?
A Well, it's not for me to comment on what the doctors themselves saw. I can only comment on what I read in the literature. And I can say that there are a variety of different articles. Some have few patients, some will have 30
09:49:00 or more patients, some may include 100 or more patients, depending, of course, on the article.
Q Now, again, I want to make sure we're clear. What is being designated as a reported rate in these two articles are what is in the literature that's being reported by a number of
09:49:19 doctors and that this reported rate is not specific to any one device. Correct?
A Correct. So that --
Q Okay. So -- the answer's correct; right?
So if you look at this, these articles, you don't
09:49:36 know what the differences are in the reported rates to

09:49:44 companies about these complications compared to what's reported to other companies; correct? You can't tell that from looking at these two articles; right?

A Are you asking, please, whether I can tell myself?

09:49:59 Q No. Nobody can tell. You can't look at these articles and say the G2, G2X, and Eclipse filter has a higher prevalence of filter migration -- filter fracture that embolized to the heart than other devices that are on the market. True?

09:50:14 A I can only say that -- I can only tell and comment on --

Q Sir, is what I just said true? That's all I'm asking. Is it true that you can't -- doctors can't look at the 2001, 2003, 2016 articles that you've been discussing and find out anything about the prevalence of any Bard product to fracture

09:50:37 and embolize into people's hearts and lungs compared to either a competitive device or any of its own devices. True?

A No, I would have to disagree with that statement. There are articles which are published at reputable hospitals and other centers that discuss the Bard device as well as

09:50:57 different manufacturers. So in terms of how a doctor would determine that, he or she would look at the reference and read that to gain that information.

Q Sir, I think you completely misunderstood my question.

My question was whether or not there's anything in

09:51:12 any of the articles, the 2001, '3, '16, article, articles,

that specifically will tell a doctor who reads them about the G2, G2X, or the Eclipse filters' propensity or prevalence to fracture and migrate to people's hearts or lungs in comparison to competitive devices and their own Simon Nitinol filter. There's nothing in the articles that will tell doctors about that; correct?

A In which set of documents, please? In the guidelines?

Q Right. There's nothing in the guidelines that talk about that. True?

A The guidelines, as has been discussed here just recently, that's correct. Do not deal with the G2X or the Eclipse.

Q Okay. And these guidelines do not deal with the company's internal tracking and trending of their own complications and the way those complications match up to competitive devices or their own devices that they're selling. True?

A That would be company or proprietary information so that that is true.

Q I think you agreed when Mr. Condo asked the question, none of these guidelines control what are acceptable and unacceptable risks with respect to what should be warned about to doctors; true? What doctors should know about a particular company's own device. They don't control that; right?

A The guidelines that we've discussed are meant for -- to educate and to inform, and that is their purpose.

Q And the guidelines don't address whether or not a product

09:53:00 is properly designed or not that might be contributing to these rates; true?

A The guidelines don't comment on that factor. Correct.

Q And they don't comment on whether or not a device is in

09:53:16 compliance with federal regulations; true?

A The guidelines do not include that commentary. All of the devices, I should say, which we've discussed here have been accepted by the FDA. So I'm trying to answer your question as accurately as possible.

09:53:37 Q The other thing I noticed about both of these when you put up the tables, there was some zeros on there. Like zero to 41 percent, zero to 100 percent. I would assume it's the SIR's position that irrespective of what may be reported in the literature about devices that go back to 1982 and 1990s

09:53:58 and even up to the present, that they want a device that is at zero or close to zero as you can get with respect to those complications that are being referenced in these articles; true?

A I cannot speak on behalf of the SIR as a whole, but I can

09:54:18 say to you certainly in the patients I treat it would be my goal, my preference, to have no complications with my patients if that were possible.

Q Okay.

MR. LOPEZ: Could we put up the 2001, Exhibit 7312.

09:54:42 May I publish, Your Honor? This is the one that just

09:54:43 got admitted --

THE COURT: This is -- yes, you may.

MR. LOPEZ: Can we go to the second page of that and go down to where it says "death" right in the first column, Felice.

09:55:22 BY MR. LOPEZ:

Q Now, this is the -- this has got one reference called the Becker article; right?

A Yes.

09:55:41 Q And I think even in 2016 it references the same article; correct?

A Yes.

Q And the Becker -- do you know the Becker article well?

A Well, I know of the Becker article. If there's a part of

09:55:56 it that you'd like me to talk about I would have to probably look at the article in order to reference it.

Q Well, the Becker article describes the type of deaths that are being reported in these two articles, these two SIR articles, do they not?

09:56:17 A In that case, that would be true.

Q And do you recall they involve deaths from a misplacement of a Greenfield filter during insertion?

A It was a procedurally related death unfortunately.

Q And cephalad migration of an early version of the bird's

09:56:34 nest filter to the pulmonary artery. Those are the four

09:56:39 deaths that are referenced in the Becker article; correct?
A Yes.
Q Now, are there any -- so this article doesn't deal with deaths caused by a filter that -- any particular filter or
09:56:53 Bard filter that may have failed as a result of a design deficiency; true?
A I can only comment on the article and say that the article and the committee reviewed any procedurally related deaths, as you described, and what filters with what -- with what filters
09:57:18 they occurred in at the time.
Q Now, there's been evidence in this case that the first retrievable filter that Bard made, out of which the rest of these devices were designed, in the first year, first few months, really, it was on the market, had a statistically
09:57:37 significantly increased risk of fatalities --
MR. CONDO: Your Honor, may we approach?
THE COURT: Yes, let's approach for a minute.
If you want to stand up, ladies and gentlemen, feel free.
09:57:50 (Bench conference as follows:)
THE COURT: Looks like we're assuming our usual sides.
Mr. Condo.
MR. CONDO: I think we're walking into the Recovery
09:58:12 death issue and Recovery death evidence and I think that's

09:58:17 been foreclosed by the Court.

THE COURT: What is it you're referring to?

MR. LOPEZ: I'm referring to the testimony that came in in Ms. Natalie Wong, she did statistical analysis of the 09:58:30 Recovery filter that showed it had a significantly increased risk of fatalities compared to other devices on the market and that didn't -- you wouldn't have known that by looking at this article. And it also opens the door, Your Honor, too, the number of deaths that are not in that article.

09:58:48 THE COURT: Let's not talk about that right now. Let's talk about Mr. Condo's issue.

If it's a reference to the Wong testimony, do you have an objection?

MR. CONDO: No if he specifically references the Wong 09:58:59 testimony. That's not where he was going.

THE COURT: Well, he did start out by saying, "There's been evidence in this case that there was a statistically significant increase of death in the Recovery."

I understood that to be referring to the Wong 09:59:14 testimony.

MR. CONDO: Wong testimony.

THE COURT: And I assume if that's what he's referring to, you're not objecting?

MR. ROGERS: No, I just want to understand the 09:59:23 parameters of --

09:59:24 THE COURT: Okay. We'll talk about that in a minute.

So what's been put in with respect to Wong, I think, is you can ask the witness about that. You wanted to --

MR. LOPEZ: Well, I mean, if the jury's going to get 09:59:37 a fair picture of what these guidelines really are to doctors, and what these rates really are, and I've got 19 deaths in a Recovery filter caused by a migration to the heart by the device being dislodged, these guys don't talk about that type of risk, Judge. You cannot look at these guidelines and say 09:59:59 there's a risk of an acceptable threshold of death for that type of event. I asked him that in his deposition. He said these guidelines do not cover that event. You cannot go to the SIR guidelines and determine by looking at them that there is any risk of a filter being hit by clot and embolizing.

10:00:24 THE COURT: Well, you just brought that out with him; right? You just had him confirm that the only deaths that are described in the article are procedurally related deaths. So it seems to me you've made the point that it doesn't cover other kinds of deaths.

10:00:40 MR. LOPEZ: Okay.

THE COURT: I'm not understanding how your question --

MR. LOPEZ: The 2016 -- we've gone down the road now 15 years. They're still talking about four different -- four 10:00:52 types of deaths for the medical community to read about

10:00:56 because Bard's not given the medical community the reality about the deaths that have occurred with their design of this filter.

THE COURT: Here's the question I have. You have established, I think, through the questions you just asked, that there's only a particular kind of death reported in the SIR guidelines. And therefore other kinds of deaths aren't reported. So that's established.

I don't see how your establishing of that limit then opens the door to your bringing in deaths that are not covered by the SIR guidelines.

MR. LOPEZ: Your Honor, to me it's simple. I hope I can say it the way I want to say it.

They've used the SIR guidelines to keep the Recovery filter on the market so it can be predicate for the G2. The Recovery should not have been on the market. And they use the SIR guidelines to do that. That the death rate was less than .12 percent. Okay?

And they use those guidelines that discuss deaths that have nothing to do with the malfunction and the design defects and the deaths that were caused by the Recovery filter. They've been abusing SIR guidelines with FDA industry since the Recovery filter.

I think I have a right to establish that starting with the Recovery filter and walking myself through the G2,

10:02:18 the G2X, and the Eclipse.

They're using that as an acceptable rate of these complications knowing that these articles, the actual guidelines reference articles that don't even describe what's
10:02:33 going on with the Bard devices. That's why it's so unfair to have these, without -- I can -- this would be a mini trial. I should be able to go through every article and establish these SIR guidelines will not tell you what's going on with the Bard filter.

10:02:48 THE COURT: I think you just asked those questions. But, okay. I understand your point.

What you're arguing is that you should be able to go into cephalad migration death evidence.

MR. LOPEZ: Because the SIR guidelines do not address
10:03:00 that. This jury thinks a .12 percent risk of death is acceptable to the Society of Interventional Radiologists because the Society of Interventional Radiologists do not know about the 20-something deaths that happened with the migration of the filter. Migration of filter after a clot hits it and a
10:03:25 it failing after that. Because it's not covered. It's not there.

THE COURT: Okay. I think I understand your point.

What's the response?

THE COURT REPORTER: I can't hear Mr. Condo at all.

10:03:44 MR. CONDO: We're trying to do a word search for the

10:03:46 Wong transcript to see if the word "death" appears.

THE COURT: I'm pretty sure it was covered; I've got it in my notes.

MR. CONDO: I know you did. That's why Ms. Helm was

10:03:56 just --

MR. LOPEZ: Can I get a drink of water real quick, Judge?

THE COURT: No. Yes.

What are you searching?

10:06:12 MS. HELM: You know how I get the transcript of the video that's being played and read through it? I'm word-searching the transcript.

THE COURT: My memory is that she talked about the statistically significant difference in death rates.

10:06:25 MR. LOPEZ: It's at the bottom.

THE COURT: Okay. Listen. How I rule on this is not going to affect what you bring out with Dr. Grassi. He doesn't know about the Bard cephalad migration deaths; right? Your argument that it's opened the door, it seems to me, is

10:06:39 other evidence that you would put it if I agreed with you.

MR. LOPEZ: He does know about it. He knows about it. He's been deposed ten times. I mean, he knows about it. He knows that this article --

THE COURT: Well, okay. If you want me to rule now,

10:06:55 I'm not persuaded that your questions limiting the SIR

10:07:00 guidelines to procedural deaths has opened the door to your bringing in non-procedural deaths. And that is essentially the argument.

I understand your broader argument, that you think
10:07:12 the jury is being misled by the SIR guideline's references to death if they don't know about the cephalad migration deaths.

I want to think about that and think about whether Wong opens that door. But I've got to go back and look in more detail at Wong. So I'm not going to say you've opened
10:07:31 the door now and you can go into cephalad migration deaths with Dr. Grassi. What I will say is you can, as you were about to do, because my memory is that she referred to statistically significant increase in death rates, ask that question about Wong.

10:07:46 MR. LOPEZ: Right. It's in there. I wasn't sure it was --

MS. REED ZAIC: I can't make it bigger, I'm sorry. And there's a second reference. 153 and 158.

THE COURT: So I'm going to allow you to do what you
10:08:08 were about to do, but you shouldn't go into cephalad migration deaths until we have addressed this further.

MR. LOPEZ: Okay, Your Honor.

(Bench conference concludes.)

THE COURT: Thank you for your patience, ladies and
10:08:20 gentlemen. We will continue.

10:08:22 BY MR. LOPEZ:

Q Dr. Grassi, I want you to assume there's been testimony in this case that Bard had done a statistical analysis of the Recovery filter in the early months it was on the market and

10:08:49 had determined that there was a statistically significant increased risk of fatalities with the Recovery filter compared to a number of other filters that were on the market at the time, including the Simon Nitinol filter.

Can you assume that for me?

10:09:08 I'm just asking you to assume that's true for the purposes of my next question. Okay?

A I'll --

Q Is that --

A Go ahead.

10:09:15 Q Is that -- is that information contained in the 2001, 2003, or 2016 SIR article? Articles.

A Is that specific information, which I would imagine from your description is internal company-conducted tests and trials, would not be included in the IVC filter guidelines

10:09:44 published by the SIR, nor would I expect it to be.

Q I want you to assume further that there's been evidence in this case that with respect to the G2, G2X, and Eclipse filter that with respect to caudal migration that the company determined that, based on what was being reported to them by

10:10:06 doctors, not medical literature but by doctors to the company,

posed an unacceptable risk of serious injury to patients, would you find that by looking at the SIR guidelines in any year that they were published?

A Again --

Q Sir, can you just answer that yes or no. Would you find that information in the SIR guidelines?

A I think it's clear, as you can see the guidelines with myself, that that information is not contained in the SIR guidelines.

Q So your answer is no, you would not find them in any of these articles we've been discussing; true?

Sir, true?

A You're going to have to please repeat your question because you asked me if --

Q I'll go on to my next question.

A -- if it would be found, and what I'm trying to explain just carefully and accurately, it is not found in reading these guidelines.

Q And if a company was selling a device that it had determined had design flaws that were increasing the risks of those complications that are discussed in the SIR guidelines, you wouldn't find that by looking in the SIR articles, would you?

A It is not contained in the guidelines, that's correct. The guidelines were not intended to publish that type of

10:11:23 information.

Q Now, Mr. Condo pointed out that in the Fracture section for the 2001 guidelines article, filter fracture, there were two references. Right? 17 --

10:11:43 MR. LOPEZ: Can we go to the references, please, Felice, so we can show -- well, first of all, go to Table 2 and -- there you go.

BY MR. LOPEZ:

Q And references 17 and 24, do you see that?

10:12:05 A Under --

Q It has --

A Under --

Q It has two references.

A Under the third line, filter fracture; is that right?

10:12:13 Q Again, this is not a threshold rate, this just happens to be what this large group of your colleagues over a two year period of time scanning the world literature, correct, found two articles they thought was relevant to filter fracture. True?

10:12:31 A That's correct on this category, yes.

Q And that was -- I mean, you looked everywhere to see what you could find out about filter fracture and you found two articles; right?

A These were the two articles which were considered to be

10:12:45 the most relevant and they were used as the citation.

10:12:50 Q So if I was a practicing radiologist from 2001 until 2016 and I was going to look at these guidelines to see what's the history of fractures with filters, Dr. Grassi and his colleagues, and later some other doctors who wrote these, 10:13:09 would refer them to reference number 17 and number 24; correct?

A Yes.

MR. LOPEZ: Can we go to the Reference section, Felice, please, and show the jury what 17 and 24 are.

10:13:23 BY MR. LOPEZ:

Q Reference 17 is an article by a Dr. Ferris and a Dr. McCowan; correct?

A Correct.

Q And the next reference is an article by Dr. McCowan.

10:13:58 A Correct.

Q Actually, it looks like written by the same two physicians, looks like they just reversed who was going to be first, right, in these articles?

A Tim McCowan and Ernie Ferris, each of whom I know, each 10:14:14 had a long-standing interest in IVC filters and were active in the field.

Q Let's look at the --

MR. LOPEZ: Can we have Exhibit 1215 -- I'm sorry, Exhibit 3608.

10:14:26 Can you show that to Dr. Grassi, please.

10:14:30 BY MR. LOPEZ:

Q This is one of the articles that was a reference to the fracture rate that doctors could refer to to find out what was going on with filter fractures; right?

10:14:44 A This is one of the articles that was referenced.

MR. LOPEZ: Can we just highlight for doctor -- so both Dr. Grassi and I can read the top part of that.

BY MR. LOPEZ:

Q This involves the Simon Nitinol -- the Simon Nitinol

10:14:58 filter; correct?

A It does.

Q And this was -- it involved 20 patients; right?

A It did involve 20 patients.

Q And there was a followup of an average of 14 months in 16

10:15:18 of the patients; true?

A Yes.

Q And they found delayed fracture of a filter, after having gone back and looked, of two patients; true?

A Yes.

10:15:29 Q That's the ten percent fracture rate that doctors think has been reported in the literature; true?

A It was two out of ten patients or a rate of ten percent in his article. That's what it appears to be.

Q Now, this article was written in 1992; right?

10:15:50 A Yes, in the JVIR.

10:15:54 Q What does Bard have in its internal files going down ten-plus years, almost 20 years, past 1992, about the fracture rate of the Simon Nitinol filter?

MR. CONDO: Foundation and exceeds scope of direct.

10:16:14 THE COURT: Overruled.

BY MR. LOPEZ:

Q Do you know?

A I can't comment on that because I'm not privy to a company or other proprietary data.

10:16:23 Q What changes did NMT, the predecessor to Bard, make to the Simon Nitinol filter to improve its fracture rates? Do you know?

A Well, what I know --

Q Sir, do you know what changes were made to the Simon

10:16:38 Nitinol filter that improved its design and fracture rates?

A Yes, I'm trying to answer your question.

Q Okay.

A It's my understanding that the Simon Nitinol filter was treated, a surface coating. That was one of the steps that

10:16:59 was taken in the refinement of the device in an effort to prevent biocompatible reactions and also give it more resistance as an improved or upgrade to the device, improvement, I should say, or upgrade to the device to give it more fracture resistance.

10:17:21 Q And did either one of the two fractures in this study

migrate to a patient's heart or lung?
A From looking at the abstract, it does not appear that that occurred.
Q Okay. Again, do you know what the current reported fracture rate is for the Simon Nitinol filter as of 2003 or '4?
A Well --
Q Sir, do you or don't you?
A Yes. Again, I'll try to answer that question. The Simon Nitinol filter, as you know, is a earlier type device, not in active clinical use now as it had been. And there have been a variety of reports on complications, including fracture rates, of the Simon Nitinol filter.

It's my understanding that after some of the refinements, such as the electropolishing, of the Simon Nitinol filter occurred, that its fracture rate decreased. There have been reports, if I'm correct, of as high as 7 to 9 percent by some investigators.

Q Sir, let me ask you this: Has Bard shown you any of their internal documents regarding the complication rates that are being reported to them by other doctors, colleagues of yours? Have they shown you any of that data?
A No, they have not shown it to me.
Q Have they shown you any data about what their -- what -- they're tracking and trending the Simon Nitinol filter. What

their reported rate is for fractures in the Simon Nitinol filter, have they shown you that data?

A No. I would not be --

Q Have they shown you any data that -- where the fracture rate is .006 percent fractures for the Simon Nitinol filter? Have you seen that data?

A No.

Q And you wouldn't know about that data by reading any of the SIR guidelines; true?

A Well, that information's not contained in these guidelines, that's correct.

MR. LOPEZ: Can we look at Exhibit 3614.

BY MR. LOPEZ:

Q This is the -- instead of McCowan-Ferris, it is the Ferris-McCowan article; correct?

A That's correct. In this first article Dr. Ernie Ferris in the study of 320 patients was the lead author.

Q And that was in 1992 was the first one and this one is 1993; correct?

A Yes.

Q And this is a little larger study. It involved 320 patients; right?

A Yes. This was a significant study at the time.

Q Was this a retrospective study?

A Let me refresh my memory on that, please, if I can refer

to it.

And if I might be able to see page 2.

Q Okay.

A And would it be possible to go back, please, to page 1?

Q Sure. If you need any of it blown up, just let me know.

In fact --

A So that on page 1 under the Materials and Methods it states from April 1985 through June 1992, 324 IVC filters were inserted in 320 patients at University hospital of the University of Arkansas for medical sciences. And without reading further, this would seem to indicate it was a cohort study of that group of patients. Meaning the number of patients that they saw over that period of time are reported on as a group in this publication.

Q How many fractures were reported in this study?

A In your question, if you could be more specific --

Q Let me ask this question --

A -- which filter?

Q Let me ask the question differently.

How many fractures reported in this study, which was like 20, 25, 30 years ago, involved a strut, piece of metal from the filter, migrating beyond the site of the filter itself and going into patient's hearts or lungs?

A Obviously it's very difficult for me to answer that question because that involves drilling down in a fine level

10:22:21 of detail. That would probably be the kind of question you'd have to direct to Dr. Ferris or Tim McCowan.

Q All right. What's reported -- these are one of your references that was reported.

10:22:34 It's true that neither the article we just looked at nor this article describes a fracture that goes beyond the site of the filter and embolizes into a patient's heart or lung; true?

A I'll take your word for that.

10:22:49 MR. LOPEZ: Can we go to the last page. It's actually not the last page. Page 855 of the article.

Go back. I'm sorry. Right before that. In the middle column. Beginning with the words "some" down -- right there. "Some complications occur many days or years after

10:23:21 filter placement."

There you go. You were just there.

BY MR. LOPEZ:

Q Doctor, see where I am here? This is the end of this article. This is one of the articles you reference for

10:23:37 fractures; right?

A This was referenced.

Q "Some complications occur many days or years after filter placement and many complications such as filter fracture, migration, and caval perforation can be asymptomatic."

10:23:51 Did I read that correctly?

10:23:52 A You did.
Q "In view of these facts, in patients with short life expectancies, such as those with terminal malignances, long-term filter complication rates may be less important than
10:24:02 ease and safety of insertion.
"In patients with longer expected life spans, the lack of delayed complications becomes more important. We believe continuous long-term followup, both clinical and radiologic, of these permanently implanted devices is
10:24:18 essential.
"A national filter registry or multicenter study of IVC filters might help resolve some of the unanswered questions regarding filter efficacy and safety."
Did I read that correctly?
10:24:31 A You did.
Q And that was something that was written in 1993; correct?
A Yes. And as you know, the Preserve trial registry is being conducted now.
MR. LOPEZ: All right. Move to strike the last
10:24:45 portion of his answer.
THE COURT: Sustained. Nonresponsive.
BY MR. LOPEZ:
Q If I were to go through many of the references in this 2001 article that Bard has used to compare its rates as
10:25:04 acceptable rates, would I find more and more --

10:25:09 THE COURT: Hold on just a minute.

MR. CONDO: I think that's a comment on the evidence. Also argumentative.

THE COURT: Hold on just a minute.

10:25:22 Restate the question would you, please, Mr. Lopez.

MR. LOPEZ: Could we look at Dr. Grassi's article, Trial Exhibit 7039. Just go to the last page.

Go to the first page first and have him acknowledge he wrote this article in 1990.

10:25:42 THE WITNESS: Yes.

MR. LOPEZ: And can we go to the last page, Conclusion portion of this.

Right there.

BY MR. LOPEZ:

10:26:08 Q Doctor, this is an article you wrote. No co-authors, this is Dr. Clement Grassi's statement in 1990; correct?

A Yes, this was an invited review article which I wrote for the American Journal of Radiology.

Q "Conclusions. A group of new, smaller percutaneous filter

10:26:27 devices are now available, each with its advantages and disadvantages as described. The ideal vena cava filter is not yet available."

Did I read that correctly?

A You did.

10:26:38 Q "Further clinical trials of these devices with randomized

prospective study are necessary in order to further refine the existing filters and to assist in the development of a filter that will be superior for the prevention of pulmonary embolism. Until that time, the choice of an IVC filter from those available should be based not only on interventional radiologist's preference, but also on the specific clinical situation and the filter's performance."

Did I read that correctly?

A Yes.

Q Filter performance meaning the device's best safety profile and effectiveness; true?

A Well, filter performance, in fairness, would include several factors, and safety and effectiveness would be two of those.

Q So 1990 Dr. Grassi, Dr. Grassi, and some of his colleagues he cited in his article in 2003 are telling industry that they need to do some clinical trials so we can find out how effective or maybe how dangerous these devices are; true?

A No, counselor. My comments in this article are directed, as you can see in the next to last sentence, to interventional radiologists. This was not a commentary to industry. I would not presume to comment to industry as to what they should be doing or not doing. I can comment on my practice as a doctor, as an interventional radiologist.

Q We heard some testimony in this trial about call to arms

10:28:12 or call to action about pulmonary embolism. Are you familiar with that document? The Surgeon General document?
A I've certainly heard of those types of health discussions for the benefits of patients, yes.
10:28:28 Q Let me ask you this question, Doctor. Based on the literature reviewed as an interventional radiologist, if I were to -- there are a number of articles where there's been a call to arms or call to action for industry to please do a study for IVC filters to see whether or not they work and to
10:28:45 tell us how dangerous they might be if we leave them in patients longer than six months, a year, two years. True?
A Yes. And that registry, the Preserve trial's, being conducted now.
Q A little too late for people who didn't get a Denali
10:29:04 filter; right? In other words, a little too late for people who got filters before the Denali filter and other filters currently on the market; true?
MR. CONDO: Argumentative.
THE COURT: Sustained.
10:29:17 BY MR. LOPEZ:
Q Sir, the Preserve trial you're talking about started when?
A It started approximately a year and a half ago. The date I would have to check exactly when Dr. Matt Johnson began with that Society of Vascular Surgery and Society of Interventional
10:29:32 Radiology, but it's been a more recent trial registry.

10:29:38 Q And that study is not going to involve the G2, the G2X, the Eclipse, the Recovery filter; true?
A Well, as you know, it involves --
Q Sir, does it involve those four devices?
10:29:48 A It doesn't because it involves more modern filter designs.
Q Those devices are now off the market; correct?
A Well those devices have had upgrades and refinements to the ones that are currently used by myself and others.
Q For safety reasons.
10:30:06 A Well, for a variety --
Q Was safety one of the reasons why they were upgraded or redesigned?
A No, I can't comment on that particular point. What I can say is with any device and with technology in general, there
10:30:23 are improvements and refinements that occur in multiple things, and filter devices are just one of those.
THE COURT: All right. We're going to break at this point. We will resume at 14 minutes to the hour.
We'll excuse the jury.
10:31:06 (Recess taken from 10:31 to 10:45.)
THE COURT: Thank you. Please be seated.
You may continue, Mr. Lopez.
MR. LOPEZ: Thank you, Your Honor.
BY MR. LOPEZ:
10:46:48 Q Dr. Grassi, I'm going to show you Exhibit 7084. It will

10:46:54 be on your screen. And I'll represent to you this is one of the articles that you reference in your report as having been an article you reviewed in preparation of your expert witness report.

10:47:04 Do you recognize the article?

A Yes.

Q And this article was published in the Journal of Vascular and Interventional Radiology; correct?

A Yes.

10:47:20 Q And these articles are peer reviewed and it is an authoritative journal?

A Yes.

Q Do you know Matthew Johnson?

A I do know Matt, yes.

10:47:31 Q How do you know Matthew Johnson?

A As a colleague and knowing him through SIR and I know him for his work in the midwest.

Q Is his article -- is this 2012 article referenced in any of the SIR articles that we've been talking about?

10:47:53 A I would have to double check because this --

Q If you don't know, that's fine. Just wondered if you knew.

A This invited commentary was in 2012, so I would have to. Double check where it was referenced.

10:48:07 Q Okay. No problem.

10:48:10 We just talked about 1992 and 1993 with those articles; right? Those were fracture articles. We're going to fast forward 20 years to 2012.

MR. LOPEZ: Could we look at twenty -- the next page.

10:48:29 And go all the way down here.

BY MR. LOPEZ:

Q As your colleague, Dr. Johnson, wrote in 2012 in this journal that "Rather than develop aggressive techniques for the removal of fractured filters, it would seem more

10:49:08 appropriate to try to prevent that complication and other complications to the greatest extent possible."

Do you agree with that?

A I believe --

Q Do you agree with the statement or don't agree with the

10:49:22 statement? That's all I'm asking you right now.

A Well, I would in fairness have to ask from you what he meant by "aggressive techniques."

I suspect Matt Johnson writing this means advanced techniques because we tend to separate filter retrievals into

10:49:38 conventional techniques and then other assisted techniques, such as laser, which has been performed by other doctors, such as you know Dr. William Kuo.

So in answering this question, I do agree with his approach that it's important to prevent complications with

10:49:57 filters. But at the same time, in my own practice, I feel

10:50:03 that removing them with --

MR. LOPEZ: Your Honor, beyond the scope. Objection.

THE WITNESS: -- judgment is employment --

THE COURT: I think he's trying to respond.

10:50:14 If you want him to answer a question yes or no, ask him to.

If he asks you to, Dr. Grassi, either answer yes or no, or, if you can't answer yes or no, tell him you can't.

All right.

10:50:22 MR. LOPEZ: I'm going to withdraw the question and ask the question again.

THE COURT: You can move on to another question.

BY MR. LOPEZ:

Q I'm going to ask him whether or not Dr -- your colleague, 10:50:33 Dr. Johnson, wrote, "Rather than develop aggressive techniques for the removal of fractured filters, it would seem more appropriate to try to prevent that complication and other complications to the greatest extent possible."

Did he write that in 2012?

10:50:49 A Yes.

Q And did Dr. Johnson also write "To that point, it is important to note that the fractured filters removed in both of the studies were almost exclusively filters marketed by Bard Peripheral Vascular, Tempe, Arizona."

10:51:07 Did I read that correctly?

10:51:08 A You did.
Q "13 of 15 in the study of Dinglasan, et al., and 63 in the study of Vijay, et al. Both articles describe removal of not only Recovery filters but also of G2 filters, and the latter
10:51:22 article also describes removal of fractured G2 Express filters."
Did I read that correctly?
A Yes.
Q "Although fracture is not a complication exclusive to Bard
10:51:32 filters, review of the literature suggests that they fracture at a much higher rate than do other filters."
Did I read that correctly?
A You do.
Q Have you ever talked to Dr. Johnson about this?
10:51:51 A I have talked to him about subjects of filters, but not this particular detail point.
Q All right. Now, would you expect that a medical device manufacturer would undertake to study its own safety issues regarding its own products?
10:52:06 MR. CONDO: Objection. Foundation. Beyond the scope.
THE COURT: I think foundation needs to be laid.
BY MR. LOPEZ:
Q Let me move on to another question.
10:52:16 You were not given open access to Bard's database of

10:52:19 internal documents; correct?
A Correct.
Q Yet you're here to talk about complication rates and the various rates of complications and risks and those sorts of
10:52:29 things with respect to IVC filters; correct?
A Yes.
Q And you know that Bard, just like all device manufacturers, is required to maintain detailed information about the injuries and complications caused by their filters.
10:52:44 True?
A Yes, as I understand, they are.
Q And you haven't been provided access to any one of those; correct?
A No, I've not been provided any of that company-specific
10:52:54 information.
Q And you understand that the plaintiffs, the people -- the lawyers that are representing Mr. and Mrs. Hyde have provided that information to our experts for their testimony and opinions. Do you understand that?
10:53:13 A I would take your word for that statement, counselor.
Q And so Bard or its lawyers have not shared with you their health hazard evaluation documents regarding their retrievable filters?
A No.
10:53:30 Q They've not shared with you their bench testing results;

10:53:33 true?
A True.
Q They've not shared with you their complaint files, I just asked you that. True?
10:53:40 A True.
Q They've not shared with you their root cause analysis for filter fracture, perforation, migration, or tilt, have they?
A No, they have not, nor have other manufacturers.
Q I know. We're talking about Bard in this case; right?
10:53:55 And they have not shared with you the statistically significant comparative analysis of complications that various of their stat -- biostatisticians have performed in comparing their devices to competitive devices and to the original predicate device, the Simon Nitinol filter; true?
10:54:15 A Correct, I've not received any of that company information.
Q Do you expect device manufacturers would adequately test a product before it puts it on the market?
MR. CONDO: Your Honor, objection. No foundation.
10:54:40 Exceeds the scope.
THE COURT: Sustained on exceeds the scope.
BY MR. LOPEZ:
Q And I think -- I'm not sure Mr. Condo asked you this question, but you would agree that the SIR guidelines, whether
10:55:06 they're the 2001, the 2003, the 2016 article, are not intended

as an instruction manual for the design and marketing and manufacturing of devices for manufacturers; true?

A That's true. They were intended as guidelines.

Q Sir, would you agree that -- I'm not going to name them all, but the ones discussed today, the SIR guidelines do not provide any information about the reported rates that might be influenced by design flaws in any Bard product; true?

A No, I couldn't say that. I would have to simply say that they report the rates and the events as described in the literature. I could only word it as simply as that.

Q So if you wanted to find out anything about whether or not a company was complying with federal regulations, industry standards, testing thresholds, insuring that a device was safe before it went on the market, you could not find that information in the articles that Mr.-- that you and Mr. Condo discussed during your direct examination; true?

A True, because those documents were intended as guidelines not to address the points that you mentioned.

MR. LOPEZ: Those are the only questions I have at this time, Your Honor.

THE COURT: Redirect.

MR. CONDO: Yes, Your Honor.

R E D I R E C T E X A M I N A T I O N

BY MR. CONDO:

Q Dr. Grassi, let me follow up on the last series of

questions.

When the Society of Interventional Radiology undertook its two-year survey of the published medical literature and then when it subsequently updated the SIR guidelines in 2016, did the SIR or the American College of Radiologists have access to the databases, complaint files, internal reporting records, of any IVC manufacturer?

A No, they did not, to the best of my knowledge.

Q And are the SIR guidelines that were published in both 2001 and 2016 intended to educate and inform persons who plant and retrieve IVC filters?

A Yes.

Q And that includes doctors who plant -- implant and retrieve Bard filters; correct?

MR. LOPEZ: Objection. Leading.

THE WITNESS: Yes.

THE COURT: Hold on a minute.

Sustained.

BY MR. CONDO:

Q Does that include doctors who implant and retrieve Bard IVC filters?

A Yes, it does.

Q Is there anything in the SIR guidelines that tells doctors who implant Bard filters that these thresholds don't apply or should not apply in their individual clinical practices?

A No, there isn't.

Q Are they in fact intended to apply in Bard -- in clinical practices where doctors implant and retrieve Bard filters?

A Yes.

MR. CONDO: Thank you. I have no further questions.

THE COURT: Okay. Thanks. You can step down, Doctor.

MR. ROGERS: Your Honor, at this time the defendants call Dr. Christopher Morris.

THE COURTROOM DEPUTY: Dr. Morris, if you would please stand right here and raise your right hand.

CHRISTOPHER MORRIS, MD,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. ROGERS:

Q Morning, Dr. Morris.

A Morning.

Q Happy Friday.

A Thank you.

Q Doctor, can you tell the jury what your profession is, please.

A I'm an interventional radiologist.

Q Where do you work?

A I work at the University of Vermont Medical Center.

Q And can you describe for the jury your educational background.

A Yes. I went to Case Western Reserve University School of Medicine in Cleveland. Graduated from there in 1985. Year after that, I spent a year doing my internship at the same institution in Cleveland.

And then I traveled to Ohio State University Hospital where I did my diagnostic radiology residency for four years.

After that I did my interventional radiology fellowship at Massachusetts General Hospital in Boston.

And then I have since then been at the University of Vermont ever since, starting in 1991.

Q Doctor, in addition to your medical degree, do you also have a masters of science?

A Yes, I do.

Q What is that in?

A That's in radiological sciences with an emphasis in radiation physics and radiobiology.

Q The jury has heard somewhat about the difference between diagnostic radiology and interventional radiology. Would you mind explaining that again.

A Certainly. Diagnostic radiology is involved with making diagnoses by interpreting medical imaging. That includes things like X-rays and CT scans, MRI scans, ultrasound studies.

Interventional radiologists are also diagnostic radiologists but we have done further training to use imaging as a guidance tool to perform minimally invasive procedures such as biopsies, drainages, angiograms, IVC filter implantations and retrievals. Those types of procedures.

Q How many years have you been practicing as an interventional radiologist?

A I've been at the University of Vermont for a little over 27 years.

Q And so as part of your responsibilities there, do you teach?

A Yes, I do.

Q And explain to the jury what you do.

A Well, we have a very active residency program in diagnostic radiology. I was the residency director for that program for a number of years.

I've also been the director of our fellowship program in interventional radiology, and we teach fellows, who are the radiologists that go on to learn specialized training in interventional radiology.

I also, throughout my career, have taught medical students because we have a medical school at the same institution, as well as other residents from other services such as surgery and internal medicine, pediatrics, OB-GYN.

I serve not only as professor of radiology but I'm

also professor of surgery.

Q Doctor, are you board certified?

A Yes, I am.

Q In what areas, please.

A I have a dual certificate in diagnostic radiology and interventional radiology.

Q Are you a member of any professional societies?

A Yes.

Q And can you tell the jurors what are some of the main professional societies --

A Society of Interventional Radiology, American College of Radiology, Radiological Society of North America, International Society of Peritoneal Dialysis.

Q And, Doctor, is there something called a senior fellow within the society of interventional radiologists?

A Yes, there is.

Q And can you tell the jury what that is.

A Well, I'm not quite sure it's designated a senior, but there is a fellow, fellowship award, in interventional radiology. I think less than ten percent of the members of the Society of Interventional Radiology become fellows. And that is basically just an honorary designation for those members that have made major contributions to interventional radiology.

Q And are you a fellow of the Society of Interventional

Radiology?
A Yes, I am.
Q And, Doctor, have you held any leadership positions within the Society of Interventional Radiology?
A Yes. For a number years I was on the IVC filter workshop series that is put on at the annual meeting of the Society of Interventional Radiology, and I was the workshop coordinator of that series for three years.
I'm also on the Standards Committee of the Society of Interventional Radiology, the Subcommittee on Complications, and as well as a number of other subcommittees such as Renal Tumor Ablation and Women's Intervention, things like that.
Q Doctor, you referenced a moment ago one of the things you do is place IVC filters; is that correct?
A Yes, I do.
Q When did you first start to place IVC filters?
A My first year of residency in radiology, so that would have been 1986.
Q And do you currently maintain a clinical practice?
A Yes, I do.
Q Approximately how many days of the week do you spend in your clinical practice?
A Five days a week.
Q That's seeing patients and performing procedures?
A Yes. That's full-time interventional radiology.

11:05:57 Q And, Doctor, since you started to use IVC filters in your residency, have you continued to do so throughout your career?
A Yes, I have.
Q And do you implant IVC filters currently?
11:06:09 A Yes, I do.
Q And do you currently retrieve IVC filters?
A Yes, I do.
Q And can you estimate for the jury approximately how many IVC filters you would have implanted yourself.
11:06:18 A I would say personally, conservative estimate, more than 800.
Q And can you approximate for the jury about how many IVC filters you would have retrieved.
A That's a little bit more difficult to estimate but
11:06:32 somewhere between 100 and 200.
Q And have you published in the peer-reviewed medical literature on IVC filters?
A Yes, I have.
Q And can you tell the jurors about one of your more recent
11:06:45 articles.
A We had a study that came out in 2017 that was related to our multidisciplinary clinic that evaluates patients that have filters that we placed, and it was related to increasing the IVC filter retrieval rate, which we were able to do by using
11:07:06 the multidisciplinary clinic.

11:07:09 Q Doctor, are you charging for your time today?
A Yes.
Q And what is the rate at which you're charging for your time?
11:07:15 A I have a flat fee of $500 per hour.
Q And prior to working as an expert witness in IVC filters, have you ever served as an expert witness in any case for C.R. Bard?
A No.
11:07:31 Q Doctor, other than being an expert witness, have you had any other sort of business relationship with C.R. Bard?
A I was a consultant for Bard roughly 15 years ago when retrievable filters were first introduced. And I did that for -- on a low-key basis for about four, five years. But I
11:07:55 haven't had any relationship since, I want to say, 2006 or so.
Q Doctor, are you going to provide the jury today opinions about IVC filters in general?
A Yes.
Q And you're also going to provide opinions about the G2X
11:08:11 and Eclipse filters?
A Yes.
Q Are you going to provide opinions that are specific to Mrs. Hyde, the plaintiff in this case, and her care and treatment?
11:08:21 A Yes.

11:08:22 Q Doctor, let's start with your general opinions. And let me ask you generally some questions about DVT and PE to begin with.

And during the course of your career, have you 11:08:34 treated patients with those conditions?

A Yes, I have.

Q And have you had patients that unfortunately have died as a result of PE?

A Yes, I have.

11:08:47 Q You've seen that in your clinical practice?

A Yes.

Q And without treatment, if an individual is -- has a DVT, what is the risk of that patient for death if they develop a pulmonary embolism?

11:09:00 A Studies have shown it's between 26 and 30 percent.

Q And are there certain tools that doctors have in order to try and treat DVT and PE and prevent PE?

A Yes, there are.

Q And so what is the primary standard for treating an 11:09:20 individual who has got a DVT or PE?

A The mainstay treatment is systemic anticoagulation.

Q And if you've got a patient who cannot be anticoagulated or who has to come off of anticoagulants for some reason, is there any alternative treatment for those patients?

11:09:40 A Only known treatment is IVC filtration.

11:09:48 Q And, Doctor, do you have an opinion to a reasonable degree medical certainty as to whether IVC filters are effective in stopping clots?
A Yes, I do.
11:09:56 Q What is that opinion?
A I believe they are effective.
Q And what is your opinion based on?
A My personal experience, review of the medical literature, as well as discussions at scientific meetings and colloquia.
11:10:11 Of that sort.
Q Let's break that down a little bit, if you don't mind, and start perhaps with the medical literature. Is that good?
A That's fine.
Q And are you aware, Doctor, of any studies which are
11:10:24 randomized clinically controlled studies about IVC filters?
A Yes, I know of two of them.
Q What are those studies?
A PREPIC 1 and PREPIC 2.
Q Doctor, the jury heard some about PREPIC 1 and PREPIC 2,
11:10:39 but it's been a while. Let's try to take those one at a time. Can you describe for the jurors what the PREPIC 1 study was and what they did.
A PREPIC 1 was a randomized control trial that came out in 1998, and there was also an eight year followup of that study
11:10:55 as well. And it was a French study. What they did was bring

11:11:01 in 400 patients, all of which had proximal DVT, deep vein thrombosis. Some of them had a PE as well, but not all of them.

And then they randomized those patients after giving 11:11:17 all of them systemic anticoagulation. So all 400 got anticoagulation. Half received one of about four or five different IVC filters and the other half did not receive a filter at all.

Then this was very interesting because then at 12 11:11:31 days they did imaging to look for pulmonary embolism. And that included asymptomatic pulmonary emboli as well as symptomatic pulmonary emboli. And they recorded what that rate was, as well as then following these patients up to two years, and then, of course, the eight-year followup period.

11:11:52 It was interesting that they found that although there was no difference in overall mortality, at two years as well as eight years there was a decreased pulmonary -- recurrent pulmonary embolism rate with the patients that had a filter, compared to the patients that did not receive a 11:12:13 filter.

Q Doctor, to break that down a little bit, the original results of the PREPIC study were published in roughly what year?

A 1998.

11:12:21 Q Then the followup study that you referred, to when was

that published?

A It was -- the follow up was about eight years after, but the actual paper came out I think like 9 or 10 years after the original study.

Q And so for your practice in treating patients with the DVT and PE, what did the results of the PREPIC 1 study mean to you?

A Well, it meant to us that filters do decrease the recurrent pulmonary embolism rate.

Q And so, Doctor, let's move on to the PREPIC 2 study. And can you describe for the jurors the design of that study.

A The PREPIC 2 study was a similar design but not quite, and I'll tell you what the distinction was. It was more recent, it was published in I believe 2012 or '14 or something like that.

It was one single retrievable filter called the ALN. It was also a French study. The ALN filter is a French filter. And they also looked at 400 patients. All of them had PE this time. And they also had to have a few other selection criteria to enter into the study.

They were all anticoagulated. About half of them received this ALM retrievable filter and the other half didn't.

The difference is, though, in this PREPIC 2 they did not look for -- asymptomatic pulmonary emboli. They only

11:13:53 looked for symptomatic pulmonary emboli at two months and at six months.

And, by the way, PREPIC 1 as well as PREPIC 2, do not really simulate real world conditions in the sense all these 11:14:08 patients were anticoagulated. Most of our patients we place a filter in are those that can't be anticoagulated. So that is a distinction as well.

But in the PREPIC 2 study, they did not find a difference, significant difference, or decrease in the 11:14:24 pulmonary embolism rate, symptomatic pulmonary embolism rate, of the patients that received the filter compared to ones that did not receive the filter.

They weren't looking for all the asymptomatic pulmonary emboli.

11:14:37 Q So in the PREPIC 1 study, Doctor, the first one done, what types of filters did that involve?

A There were about four or five different ones. They were all permanent filters such as the Greenfield and the VenaTech, the two biggest ones, I believe, that they used.

11:14:56 Q That was a French study?

A French study.

Q Both of these studies were French studies?

A Yeah, both of them were multi-center French studies.

Q Do you recall the VenaTech filter was involved in both of 11:15:07 these?

11:15:08 A Yes. No. Only in the first one, PREPIC 1.

Q Okay. And the PREPIC 2 study, did it involve retrievable filters.

A It was only one single retrievable filter called the ALN

11:15:19 retrievable filter.

Q And so for you and your practice, what was your takeaway from the results of the PREPIC 2 study?

A Not much because I don't think it really told us a lot because it didn't simulate real world conditions and, also,

11:15:33 they didn't look for asymptomatic pulmonary emboli.

We know most pulmonary emboli are asymptomatic. We know that from imaging studies.

Q And in the community of interventional radiologists, have you and your colleagues continued to use retrievable IVC

11:15:51 filters after the results of the PREPIC 2 study were published?

A Yes, of course.

Q Doctor, are you aware any of other what we call randomized clinically controlled studies regarding IVC filters?

11:16:05 A There was a pilot study that came out of University of Florida, but it was not related to patients that had documented thromboembolic disease, it was looking at prophylactic IVC filters. I think there was a multi-center trial in Australia, same sort of nature. Again, not patients

11:16:23 that have documented thromboembolic disease. These are trauma

patients do not have DVT or PE.

Q And are you aware of any randomized clinically controlled studies that have taken a population of patients who have a DVT or at a risk of PE and have not received any treatment whatsoever and compared that to a group of patients who have a DVT and are at risk of PE but who have an IVC filter in place?

A I'm not aware of any, no.

Q Would there be issues in doing such a study?

A I think there would be major issues. I think it would be unethical to perform a study like that.

Q What's the ethical issue?

A Well, because one side of the arm would be untreated and they would be subjected to 26 to 30 percent death rate if they had a pulmonary embolism. We didn't know what it would be if they had a DVT, but it would still be significantly high.

Q So, Doctor, are there other types of studies on IVC filters that inform your opinions about whether they are efficacious?

A I believe there are lots of observational -- what we call observational type studies that show a benefit of IVC filters. Yes.

Q Are you prepared to tell the jury about a few of those?

A Yes. I reviewed many of them. Four that come to mind include Proctor and Greenfield, came out in 1997.

Q Let me stop you. Why don't we stop and talk about that

for a minute. What is that study and what did it show?

A Well, Mary Proctor was an associate of Dr. Greenfield who invented the Greenfield filter and they did a lot of collaborative studies together.

They were at the University of Michigan. They looked at a single center, University of Michigan, and their experience with PE patients. To make a long story short, they basically found that the patients that were hospitalized with PE that received a filter had a 18 percent PE-related mortality rate, but those who didn't receive the filter had a 44 percent PE-related mortality rate. So they concluded filters were significantly helpful in those type of patients.

Q And is there another large observational study you wanted to discuss with the jury?

A Well, I know lots of them. There was probably other database type study, it was a community based study published by Spencer in 2010. That group looked at VTE, or venous thromboembolic, patients. Those are the ones that have PE or DVT. We lump them all together and call it VTE. And that was about 1500 patients in the Worcester, Massachusetts area hospitals.

And they basically found that the PE -- recurrent PE rate at three years was significantly lower with the patients that had a filter versus those that did not get a filter. And the difference of the percent are like 1.7 percent to

11:19:28 5.3 percent. So like a three-fold difference.

Q Doctor, you've seen many other studies of that same nature that are large observational studies --

A Yes, sir, I have.

11:19:38 Q I'm sorry, let me get the question out. That's okay.

Have you seen other large observational studies that you believe support your opinion that IVC filters are efficacious?

A Yes, I have.

11:19:51 Q Doctor, let's switch gears. You had said another basis for your opinion that IVC filters are effective in stopping clots is personal experience; is that right?

A Yes.

Q And so let me break that down with you a little bit. When

11:20:07 you first started your career as an interventional radiologist, what type of filter were you originally trained to put in patients?

A The original Greenfield filter.

Q And was that filter kind of the gold standard filter for a

11:20:24 number of years?

A Quite a long time, yes.

Q What was your personal experience with the Greenfield filter?

A We had a very positive experience with it. We placed it

11:20:33 in all of our patients. Was a primary filter. We were one of

the first centers to use it in the trauma population back in the early 1990s. That was our mainstay IVC filter throughout the 1990s.

Q Was the Greenfield filter a permanent filter or a retrievable filter?

A Permanent filter.

Q So once that filter was implanted, it remained typically in the patient for the remainder of their life?

A Yes.

Q And so, Doctor, over the course of your career, moving on from the '90s, were other permanent IVC filters introduced into the marketplace?

A Yes, there were.

Q Can you describe for the jurors briefly what some of those filters would be?

A Sure. The cook bird's nest filter. We already talked about the VenaTech filter and the VenaTech low-profile filter. The Simon Nitinol filter. The OptEase -- sorry. The TrapEase. These were all permanent filters, all introduced in either the late '80s, mid to late '80s, or the '90s.

Q And are those all filters you had experience with personally?

A Yes.

Q You placed all of those filters?

A Yes.

11:21:44 Q Doctor, let's move on through time a little bit. So did there come a point where retrievable filters started to appear in the market and be available to interventional radiologists such as yourself?

11:21:54 A In the United States in the early 2000s we had the availability to place retrievable filters, yes.

Q And so what was the first retrievable filter you had experience with?

A It was the Cook Tulip filter.

11:22:08 Q And did the Cook Tulip filter have a limited time during which it could be indwelling in the patient?

A Yes. We called it a limited window of retrievability. We thought it was anywhere from 14 to 21 days.

Q So what did you have to do if you had a patient where you

11:22:25 had implanted one of these Cook filters and you were approaching that outside window of the 14 days?

A We had to bring these patients back down to the interventional radiology suite and essentially reposition. Collapse the filter like we were going to remove it and

11:22:42 instead of removing it out of the body, we had to redeploy it maybe a centimeter inferior or superior from where its original place was so it had a new positioning, and then we could buy them another 14 to 21 days. Sometimes we had to continually do that multiple times out to six months in some

11:23:00 of these young trauma patients in order to do that. Became

very onerous and relatively high risk for these patients to keep doing this invasive procedures.

Q And did you ultimately also have experience with the Bard Recovery filter?

A Yes, we did.

Q And did the Recovery filter offer different treatment options for the interventional radiology community?

A Yes. Right away we realized it could stay in a lot longer. So it's duration of retrievability was, we thought at least initially, was six months.

Q And so what did that mean for you and the treatment of your patients who are at risk of pulmonary embolism?

A Well, we didn't need to bring them back down continuously to reposition these filters and we could wait until we needed to retrieve it and then remove it if necessary.

Q And what was your experience with the ability to retrieve the Recovery filter at the longer indwelling periods?

A It was very favorable. I mean, we soon learned that lot of people were taking this filter out much longer than six months and there were reports early on they were being taken out after a year. So some of our patients had it in longer if they needed to have it in longer.

Q So did you have patients that, because of the Recovery filter, who would have had protection from PE that otherwise would not have had protection from PE?

11:24:22 A Yes.
Q And, Doctor, have you continued over the course of time to use the family of Bard retrievable filters?
A Continuously, yes.
11:24:32 Q And did you implant and retrieve the G2 filter?
A Yes, we did.
Q And did you implant and retrieve the G2X filter?
A Yes.
Q And did you implant and retrieve the Eclipse filter?
11:24:45 A Yes.
Q And have you implanted and retrieved the Meridian filter?
A Yes.
Q And is the same true of the Denali filter?
A Correct.
11:25:00 Q And, Doctor, can you estimate for the jury approximately how many Bard retrievable filters you would have placed over the course of your career?
A It's hard to say. I would say around 200 or more.
Q And do you have an opinion as to a reasonable degree of
11:25:14 medical certainty as to whether the Bard G2X filter and the Eclipse filter are effective in capturing clots?
A I believe they are --
MR. O'CONNOR: Objection.
THE COURT: Hold on just a minute.
11:25:23 MR. O'CONNOR: Nothing in the report about the

Eclipse filter being effective.

THE COURT: Can you show me where it is in the report?

MR. ROGERS: I'll move on, Your Honor.

THE COURT: All right.

BY MR. ROGERS:

Q So, Doctor, let's -- in addition to the Bard family of filters, have you used other retrievable filters?

A Yes.

Q What are some of the retrievable filters you've used other than Bard?

A Other than, you know, the Cook Tulip, which I already mentioned. The OptEase. The Crux. And I think that's -- oh, the Cook Celect. Those are our main ones that we've used.

Q So let's talk and switch gears and talk about the retrieval of an IVC filter.

What do you do as treating doctor to consider when is the time to remove a retrievable filter?

A Well, we have a multidisciplinary clinic that we utilize and that consists of trauma surgeons, who aren't putting many filters in now but they used to a few years ago. Mainly it's the interventional radiologists in our institution. Our hematology experts have a keen interest in thrombosis and hemostasis are the ones that evaluate our patients for when the best time to remove the filter may be.

So we refer -- make a clinic referral to our hematology specialists, and they are the experts in determining all of the different medical issues that may be affecting that patient and then refer that patient back to us for removal when indicated.

Q And do some filters when they're implanted as a retrievable filter, do they remain in a patient on a permanent basis?

A They can, yes.

Q And what are some of the reasons that a doctor may decide for the patient that the filter should remain as a permanent filter?

A Yes. In a lot of our patients, they may not -- that have a filter remain in place long term, they may not have a continuing indication for IVC filtration, but they may have some other issues that supersede that. Such as a limited life expectancy.

Say a cancer patient that may only be expected to live 10, 12 months. We feel it's compassionate not to subject them to another filter -- to another procedure to take out their filter. So that type of situation. Or maybe a very elderly patient. Someone who is 96 years old. We're not going to necessarily bring that patient back for another invasive procedure.

Q And, Doctor, are some patients -- do they have a filter

that does not get retrieved because they're what's called lost to followup?

A That does occur, but that is very rare with us now.

Q And what does that mean?

A That means that they may move away and we lose contact with that patient, or that patient may be noncompliant, not hold their appointments to come back to be assessed, clinically assessed, about removing their filters. There's lots of issues that may be in play when they're lost to followup.

Q And over the course of your career, have you seen the community of interventional radiologists take different approaches over the course of time to the removal of retrievable filters?

A Yes.

Q And can you describe for the jury what that means?

A What I've outlined what our approach has been, to use a multidisciplinary clinic approach. Others have used their own service. We all see patients in our clinics. We have an interventional radiology clinic and some of our colleagues around the country are very diligent and dedicated about bringing patients back to their own clinic and they make the call about whether or not to remove the filter for instance.

Q Doctor, are you familiar with the a safety communication that the FDA issued about retrievable filters in 2010?

11:29:10 A Yes, I am.

MR. ROGERS: Scott, would you mind pulling up Exhibit 6993, please.

And, Your Honor, we move this into evidence.

11:29:27 MR. O'CONNOR: I thought it was in. But no objection.

THE COURT: Let me check and see.

MR. ROGERS: I don't believe it is, but I may be --

THE COURTROOM DEPUTY: It's not in.

11:29:37 THE COURT: It's not in evidence.

Did I hear no objection?

MR. O'CONNOR: No objection.

THE COURT: 6993 is admitted.

(Exhibit 6993 admitted.)

11:29:45 MR. ROGERS: May we publish?

THE COURT: You may.

BY MR. ROGERS:

Q So, Doctor, up on your screen can you see the FDA safety communication?

11:29:53 A Yes. It is pretty small print but I can read it.

Q Fortunately, we can make it bigger for all of us.

And is this something that you were cognizant of when it came out in 2010?

A Yes.

11:30:07 Q And so, Doctor, you have reviewed this in the past?

11:30:11 A Yes, I have.
Q And so let's take a look at it, if you don't mind. Does it appear to you it was issued in August of 2010?
A Yes.
11:30:20 MR. ROGERS: Scott, if you would, can you pull out the section that says Audience, please.
BY MR. ROGERS:
Q And so, Doctor, who was this safety communication directed toward?
11:30:33 A Interventional radiologists; interventional cardiologists; vascular surgeons; emergency room physicians, parentheses trauma; bariatric surgeons; orthopedic surgeons; and primary care physicians.
Q And are those doctors who would be within the community of
11:30:48 doctors who may either implant IVC filters or who may run into patients who have an IVC filter?
A Yes, they are.
MR. ROGERS: And Scott you can take that down.
And, let's go down to the section that says Summary
11:31:06 of Problem and Scope.
If you would, if you'd pull that out, please.
BY MR. ROGERS:
Q And, Doctor, I'm not going to read this to you, but what is your understanding what the FDA's purpose was in issuing
11:31:18 this safety communication?

11:31:20 A Well, they were illustrating that IVC filters have long term -- are associated with long-term complications and that essentially there has been -- at this point there had been sort of a failure of communication between the implanting
11:31:37 physicians and the physicians taking care of these patients to get these patients back and to clinically reassess them about -- particularly with these retrievable filters, about removing them when they're no longer indicated.

Q So do you sometimes have patients who receive a
11:31:56 retrievable IVC filter who have what you called an indication for the filter but then later the indication goes away?

A Yes.

Q Can you give the jury an example what that may be?

A Well, let's say that a patient is diagnosed with pulmonary
11:32:09 embolism and they have a contraindication to anticoagulation. They may be a hemophiliac or something like that. And so they have -- they get a filter to protect them from a recurrent pulmonary embolism, which can be a lethal event.

And we know that after roughly between three months
11:32:32 and six months the original DVT that they most likely had experienced has stabilized and therefore they generally do not need to be further treated prophylactically against that recurrent pulmonary embolism. So after that three or six month window, it is safe, then, to remove that filter.

11:32:50 Q Doctor, let's take a look here at the last sentence that

11:32:53 is on the screen. If you'd just read along with me I'd appreciate it.

It says, "Know long-term risks associated with IVC filters include but are not limited to lower limb deep vein 11:33:08 thrombosis, filter fracture, filter migration, filter embolism, and IVC perforation."

Did I read that correctly?

A You did.

Q And were those all risks of retrievable IVC filters that 11:33:23 were known in the community of doctors who used IVC filters in 2010?

A Very much so, yes.

Q And did you -- were you personally aware of this before this publication came out from FDA?

11:33:35 A Yes.

MR. ROGERS: Okay, Scott, you can take that down, please.

BY MR. ROGERS:

Q Doctor, let's talk a little bit more about some of these 11:33:47 risks, and we just identified some, but are those risks that you just identified, are those associated with all IVC filters?

A Yeah, pretty much. There may be a few that may be uniquely excluded. For instance, the design of the OptEase 11:34:03 filter makes it so that perforation or penetration is very

rare with that filter. Just as an example.

MR. O'CONNOR: Not in this report, Your Honor.

THE COURT: Is this in the report?

MR. ROGERS: No, Your Honor.

THE COURT: Objection is sustained.

MR. ROGERS: I'll be glad to move on.

BY MR. ROGERS:

Q Well, let me kind of change gears on you, ask a little bit different question.

The public health notice we were just looking at, did that have an impact on the community of doctors who utilize IVC filters?

MR. O'CONNOR: Objection. Lack of foundation.

THE COURT: Overruled.

THE WITNESS: Yes, it did.

BY MR. ROGERS:

Q And what was that impact?

A I think it brought up to the forefront this issue that, at least in my world, interventional radiologists need to be very proactive and bring these patients back and clinically reassess them and determine when the best time to take that filter out is and not just forget about these patients, like we were doing with permanent filters.

Q And is there such a thing as a perfect filter with no complications?

11:35:01 A Does not exist.
Q Let me follow up on what you just said a moment ago.
Did you -- within your practice, do you perceive a difference between the amount of followup that patients would
11:35:11 get who received a permanent filter versus a retrievable filter?
A Yes.
Q And what is that differential?
MR. O'CONNOR: Objection. Not in the report.
11:35:19 THE COURT: Where's that in the report?
MR. ROGERS: Your Honor, it is in the generic report page 9, paragraph 4.
The paragraph that begins "Despite the fact." Do you see that?
11:36:01 THE COURT: Oh. Yes.
MR. ROGERS: Second sentence.
THE COURT: That looked like paragraph 3 to me.
MR. ROGERS: I'm sorry.
THE COURT: Objection's overruled.
11:36:13 BY MR. ROGERS:
Q So, Doctor, do you recall the question?
A Yes, I do.
Q And so can you explain for the jurors why you think that permanent filters retrieve -- that retrievable filters don't
11:36:25 receive as much scrutiny perhaps as -- I can't get this

11:36:28 question out. Let me try again.

So, Doctor, can you explain for the jury why you believe that permanent filters don't get as much scrutiny as retrievable filters.

11:36:37 A Because when we place permanent filters, we were never planning to ever remove that filter and so we did not evaluate them with imaging or through clinical parameters because we were never going to remove that filter. So most of those filters did not get imaged.

11:36:55 Whereas with the retrievable filters that we were placing, we scrutinize them because every time we would take out that filter we're going to be intensely imaging that filter. So they got a much more robust imaging followup that did not exist with the permanent filters the generation

11:37:12 before.

Q And, Doctor, do you believe that that differential may account for why there are reports of more complications with retrievable filters versus permanent filters?

A I believe that is part -- part of the issue, yes.

11:37:25 Q Doctor, let's switch gears and talk a little bit about the Simon Nitinol filter. And I believe you said that is a filter that you've used; correct?

A Yes.

Q And when would be approximately the last time that you

11:37:35 would have implanted a Simon Nitinol filter?

11:37:38 A For me personally it's been probably 20 years.
Q And is the Simon Nitinol filter a permanent only filter?
A Yes, it is.
Q And in your experience, did you see patients who had an
11:37:55 indwelling Simon Nitinol filter who experienced complications?
A Yes.
Q Can you describe for the jury what some of those
complications were?
MR. O'CONNOR: Apologize, Your Honor, but I do not
11:38:04 see this in his report.
THE COURT: Mr. Rogers.
MR. ROGERS: Your Honor, this is covered in his
deposition, July 2017, pages 151 to 153.
THE COURT: Objection's overruled based on page 153
11:39:30 starting at line 16.
MR. ROGERS: Thank you, Your Honor.
BY MR. ROGERS:
Q So, Dr. Morris, can you describe for the jury some of the
complications you saw with the Simon Nitinol filter in your
11:39:42 personal experience.
A Well, the most dramatic complication that we saw was it's
eccentric positioning or deformation, which basically -- the
best way to describe it is that the upper daisy wheel would
fold in on itself. Sort of equivalent to a tilt. And I don't
11:40:04 know if it was because it also brought the wall of the cava

11:40:08 with it and created a narrowing or whether there was so much metal now in a horizontal position, but that seemed to increase the thrombosis rate of the inferior vena cava. So we saw a number of IVC thromboses with Simon Nitinol filter.

11:40:24 Q And what does that mean if you have a thrombosis in the IVC?

A Well, the patient may be asymptomatic when that occurs, but it can also be a life-threatening a situation. It's called phlegmasia cerulea dolens. Latin term for basically a

11:40:42 surgical emergency. But now interventional radiologists treat that with thrombolytic medications. But it's a very significant situation. None of the blood from the lower extremities can get back up to the heart in that case.

Q Is thrombosis essentially a clot?

11:40:58 A Yes. Clot.

Q If there's an occlusion via a clot, does that block off the entire blood flow from the lower extremities from coming back up to the heart?

A Yes, it does.

11:41:10 Q So what sort of symptoms might these patients experience if that happens?

A Pain. Hypotension, low blood pressure. Severe swelling of the lower extremities. And ischemia. That means basically not only can the blood not get back but the swelling is so bad

11:41:32 that it's also constricting the arterial flow down to the feet

and legs, and so the patients can lose their limbs, their legs, because of that.

MR. O'CONNOR: Objection. Your Honor, this is beyond the report and beyond the deposition pages we just looked at.

THE COURT: Where is this disclosed?

MR. ROGERS: Same deposition, Your Honor.

THE COURT: Same pages?

MR. ROGERS: Yes, Your Honor.

THE COURT: Objection is sustained.

MR. ROGERS: Thank you. We'll move on.

BY MR. ROGERS:

Q Doctor, are you aware of literature that has examined complication rates with the Simon Nitinol filter?

A Yes.

Q Are you aware of a long-term study that looked at complication rates with the Simon Nitinol filter?

A By Poletti, yes.

MR. ROGERS: And, Scott, would you mind bringing up Exhibit 7226, please.

BY MR. ROGERS:

Q And, Doctor, do you see this article on your screen?

A Yes, I do.

Q Would you mind telling the jury what the title of this article is.

A This was The Long Term Results of the Simon Nitinol

Inferior Vena Cava Filter.

Q And, Doctor, what journal was this study published in?

A This was published in the Journal of European Radiology, the cardiovascular radiology section.

Q Is that authoritative journal?

A Yes, it is.

Q And is this a peer-reviewed article that would appear in the medical literature?

A Yes.

Q And, Doctor, if you would, tell the jury when this study was published.

A I believe it came out in 1998.

Q And at that point in time do you know roughly how long the Simon Nitinol filter would have been on the market?

A About ten years. Maybe a little longer than ten years.

Q And so can you describe for the jury the basic design of this study. What were these researchers trying to do?

A They were -- this is the first, and as far as I know the only, long-term study of the Simon Nitinol. There were a few evaluations of it early on after a few years that it was on the market, but this looked at the Simon Nitinol at about almost three years. I think it was 32 months.

Q And so how many patients were originally enrolled in this study?

A They looked at 114 patients originally.

11:43:50 Q And did they follow these patients over the course of time?

A Yes, they did.

Q And so at the end of this study, how many patients were

11:43:57 still -- made it all the way through the review period for those patients?

A I believe it was 38 patients got their extensive imaging followup, which consisted of X-ray, abdominal X-ray, and the average followup here was 32 months. They also got a

11:44:15 ultrasound study to look at patency of the inferior vena cava, and they also got a CT scan of the abdomen and pelvis at the same time. So all three of those imaging studies.

Q What is patency?

A Patency means whether or not it's open.

11:44:29 Q Meaning there's no occlusion?

A Right.

Q And so, Doctor, why was it only 38 patients out of the original 114 reached the end of the review period for those patients?

11:44:40 A Some of them died. These are very often very sick patients that are getting these filters. Some were lost to followup, and some just didn't consent to have all those imaging studies performed.

Q And, so, Doctor, let's go to page 292 of this article.

11:44:58 MR. ROGERS: And I'm looking for Table 2, if you can

pull that up, please, Scott.

There we go.

BY MR. ROGERS:

Q And so, Doctor, can you tell the jury what the results were about some of the complications that were observed in the Poletti study?

A Yes.

Well, first of all, there was a strut -- a strut fracture of around 16 percent. And these struts perforated the IVC at a rate of 95 percent.

And 76 percent of patients had what we consider a grade 3 perforation, meaning one of their struts was interacting with an adjacent structure around the IVC.

And then about 68 percent of these patients had what we call the eccentric positioning, meaning that daisy wheel sort of bending and collapsing on its itself.

Q Were any of these patients that were in this Poletti study on the Simon Nitinol filter symptomatic?

A No, they were not.

Q And that's despite a 95 percent perforation rate in that study?

A Correct.

Q And what was the percentage of individuals in that study that had perforation of their IVCs by the filter that was interacting with other organs?

11:46:31 A 76 percent.
Q And none of those patients were symptomatic?
A No.
Q And let me ask you, before we leave this, I do want to ask
11:46:42 you about what the authors of this study found about IVC occlusions. Can you describe that for the jury, please.
A If we look at the table on the -- under the Doppler ultrasound, they found surprisingly that in all 38 patients the IVC was patent.
11:47:00 Q And did they also examine via autopsy patients who expired during the study?
A Yes.
Q Do you recall what they found on some of those --
A There were some occlusions on the patients that died
11:47:12 during the study period.
MR. ROGERS: Okay, Scott, you can pull that down, please.
BY MR. ROGERS:
Q And, Doctor, over the course of your career, do you try to
11:47:22 stay abreast of the medical literature regarding studies that are published about IVC filters?
A Yes, I do.
Q And have you seen the various risks that we just discussed, things like IVC filter perforation and fracture,
11:47:38 have you seen that reported in the medical literature about a

11:47:41 number of different types of filters?
A Yes.
Q And are perforation, tilt, migration, fracture of IVC filters, are those known complications with all filters?
11:47:54 A Yes.
Q Was that all known to the community of IVC filter users in 2011?
A I believe so, yes.
Q Doctor, let's move on again, and I want to spend a little
11:48:08 bit of time with you talking about instructions for use that come with IVC filters. Is that something that you're familiar with?
A Yes.
Q And have you reviewed over the course of your career the
11:48:19 instructions for use that accompany the Bard family of filters?
A Yes, I have.
Q And would that include the G2 filter?
A Yes.
11:48:35 Q And before I ask you some specific questions about that, let me ask you this: Is the IFU the sole source of information that you rely on to inform yourself about the potential benefits and risks of the IVC filter?
A No.
11:48:54 Q And what are some of the other things you rely on to keep

yourself informed about what those benefits and risks are?

A The medical literature. My own personal experience. Discussing these topics with my colleagues around the country and around the world, essentially, at various venues. What I was taught during my training, my residency, fellowship, those types of things.

Q And those are all things you consider in addition to the information that's contained in an IFU?

A Yes.

Q All right.

MR. ROGERS: Scott, would you mind pulling up Exhibit 5286, please.

And, Your Honor, I move this into evidence.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit 5268 admitted.)

MR. ROGERS: May we display?

THE COURT: You may.

BY MR. ROGERS:

Q Doctor, is this on your screen, is that an IFU for the G2 filter?

A Yes, it is.

Q And was the G2 filter the predecessor to the G2X filter?

A Well, there was G2 Express in between them, but, yes, it was one of them.

11:50:12 Q Very good point. Are the G2 Express and G2X the same filter?

A The actual filter is the same. The delivery device is slightly different.

11:50:21 Q Okay. Let's take a look at one section of this.

MR. ROGERS: And, Scott, if you would go to page 3, please.

Do you see that section right in the middle that's bolded. Go down. You see where it says "Note," can you pull

11:50:35 that paragraph out, please.

BY MR. ROGERS:

Q And can you see that, Doctor?

A Yes, I can.

Q And if you would, if you would just read along with me

11:50:45 again. This particular provision says, "Note: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters, either permanent or retrievable, be tracked and receive routine followup subsequent to the placement of the device."

11:51:04 Did I read that correctly?

A Yes, you did.

Q And so was that information that was already known to you before you would have seen it in an IFU?

A Yes.

11:51:13 Q And what does this provision mean to you as a

11:51:15 interventional radiologist?
A Well, as I mentioned before, in practice we were not following permanent -- patients that had a permanent IVC filter in, but with the filters that could potentially be
11:51:27 retrieved, we believed that this was a further recommendation that these patients needed to be followed up and then determine when the best time to take that filter out if it had limited indication for filtration.
Q And has this particular provision been in the IFUs for the
11:51:51 Bard family of retrievable filters starting with G2?
A Yes.
Q So it would have been in the G2X and the Eclipse IFUs?
MR. O'CONNOR: Objection. Not in his report.
MR. ROGERS: I'll move on, Your Honor.
11:52:03 THE COURT: All right.
MR. ROGERS: Can we take that down, please.
And then go to the Complication section.
Scott, if you would, would you pull out the second bullet point, please.
11:52:27 BY MR. ROGERS:
Q And, Doctor, if you would read along with me again. Does this read "Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters
11:52:42 requiring the retrieval of the fragment utilizing endovascular

and/or surgical techniques."

Did I read that correctly?

A Yes.

Q And, again, was this information that you were independently aware of other than this IFU?

A Yes.

Q And, Doctor, was this information that was available to the community of users of IVC filters in 2011?

A Yes.

Q And was this information contained in the IFU for the G2X filter?

A Yes.

Q Was it contained in the Eclipse filter IFU?

MR. O'CONNOR: Objection. Not in the report.

THE COURT: Your response?

MR. ROGERS: Your Honor, I refer to the generic report, pages 11 and 12. It's the last sentence on page 11 and it carries over.

THE COURT: Objection sustained. That doesn't say anything about the G2X and Eclipse IFUs, as I read it.

MR. ROGERS: Okay. Thank you, Your Honor.

BY MR. ROGERS:

Q Dr. Morris, I want to shift gears a little bit and talk to you now about your specific opinions about Mrs. Hyde. And let me begin by asking you, did you review Mrs. Hyde's medical

11:54:20 records?
A Yes.
Q And can you approximate for the jury roughly how many pages of medical records you would have reviewed?
11:54:28 A Many hundreds if not thousands.
Q And did you review all of Mrs. Hyde's medical records that were available that existed prior to the implantation of her filter?
A Yes.
11:54:39 Q And did you review all of the medical records and imaging that was available between when her filter was implanted and when it was removed?
A Yes.
Q And have you reviewed medical records that exist after her
11:54:54 filter was retrieved?
A Yes.
Q And what is the most recent records, what period of time are they from that you have reviewed?
A I believe in 2018.
11:55:06 Q Did you review a number of different imaging studies for Mrs. Hyde?
A Yes.
Q Okay. And let's start this discussion with February 2011. Do you know the period I'm talking about?
11:55:19 A Yes.

11:55:20 Q And what was the medical issue that took Mrs. Hyde to seek medical care in February of 2011?
A Well, she was diagnosed with a DVT of her right lower extremity.
11:55:33 Q And did she have a prior history of having pulmonary embolism?
A She -- yes.
Q And when she presented on that date in the hospital, was a CT scan performed?
11:55:49 A Yes.
Q And the purpose of the CT scan would have been what?
A To look for a pulmonary embolism, a PE.
MR. ROGERS: Let's pull up Exhibit 8485.
Your Honor, I move this into evidence.
11:56:10 MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit 8485 admitted.)
MR. ROGERS: May we publish?
THE COURT: Yes.
11:56:16 BY MR. ROGERS:
Q Doctor, do you see on your screen there an image?
A Yes, I do.
Q Can you describe for the jury what this is. What are we seeing?
11:56:25 A This is a coronal reformatted section that was obtained

11:56:31 during the CT angiogram of her pulmonary arteries, and this particular coronal section, these are sort of in the frontal direction.

Q Let me stop you there. When you say coronal section, can you tell the jury what you mean by that.

11:56:44 A Right. So the CT scans are acquired in the axial, or cross-sectional bread loaf type acquisition. But then the computer can reconstruct the images in any different plane that we need it to. And typically they're often reconstructed in the side view, called the sagittal, and this view, called coronal, which is front to back.

11:57:03 And so this is a slice of that dataset that is front to back, sort of in the middle of her chest, to look at her -- in particular her right pulmonary artery.

Q Just to make sure that I understand what you mean by that, so when a CT is done, the original slice is what you called axial?

A Yes. Axial.

Q Do those slices move up the body in this direction?

11:57:32 A Yes.

Q You described it as kind of bread loaf sort of fashion.

A Yes.

Q So about how much space in between each of those sections when an image is taken?

11:57:42 A It varies depending what the parameters are set to, but

11:57:45 they can be anywhere from five millimeters to sub-millimeters, 0.25 millimeters, for instance. So they can be pretty, pretty thin.

Q Doctor, I believe you said this is what you said was 11:57:59 called a coronal image.

A Yes.

Q And so does that look at slices of the body moving from the front of the body to the back of the body?

A Yes.

11:58:08 Q So what organ are we seeing here?

A We're seeing both lungs. If I take the cursor here, I can show this is -- the black area is the right lung and over on her left side, this is the left lung.

This is the heart.

11:58:22 All of the white area here is the gadobenated contrast media that's injected, also known as the dye.

This is the slice through the right pulmonary artery. And then you notice there's a dark area here. This is all her clot that's on the right side of her lung extending from 11:58:42 her -- essentially that lower end of the right main pulmonary artery and into what we call lobar arteries involving her middle lobe and her lower lobe of her right lung.

Q So is that dark area you just described, is that all portions of the lung that are being deprived of blood flow?

11:59:02 A Yes. So this would be -- all this area of the lung down

here would be deprived of blood flow, yes.

Q All right. Let's move on --

MR. ROGERS: You want me to stop --

THE COURT: We're going to break at this point.

Members of the jury, we will break until 1 o'clock. Please remember not to discuss the case or do any research. We'll see you then.

(The jury exited the courtroom at 11:59.)

THE COURT: You can step down, Doctor.

Counsel, let me give you your time.

As of the lunch hour, plaintiffs have used 28 hours and 40 minutes. Defendants have used 14 hours and 28 minutes. And we will see you at 1 o'clock.

MR. ROGERS: Thank you, Your Honor.

(Recess taken from 12:00.)

(End of a.m. session transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 29th day of September, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter